EC 2-3-6-84

Commission on Complementary Medical Methods

Final Report

December 1, 1995

State of Maryland

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
201 WEST PRESTON STREET • BALTIMORE, MARYLAND 21201 • Area Code 410 • 225-

Parris N. Glendening
Governor

Martin P. Wasserman, M.D., J.D.
Secretary

COMMISSION ON COMPLEMENTARY MEDICAL METHODS

December 1, 1995

The Honorable Parris N. Glendening
Governor
State House
Annapolis, Maryland 21401

Dear Governor Glendening:

On behalf of the State Commission on Complementary Medical Methods, I am pleased to submit our final report.

The thirteen member commission was appointed two years ago by then-Governor William Donald Schaefer for a one year period as mandated in House Bill 382. Senator Idamae R. Garrott was instrumental in extending the deadline an additional year through Senate Bill 246.

The charges of the commission were as follows:

-to define which health care methods are complementary medical methods
-to evaluate the costs, benefits, and risks associated with the use of complementary medical methods
-to study how to allow the use of complementary medical methods by Maryland physicians with patients who wish to be treated with complementary methods for their medical conditions

Without the support of the physicians in the State of Maryland, completion of this report would have been impossible. We thank the Legislature for allowing us to serve it and the citizens of the State of Maryland.

Sincerely,

Caril E. Price, Ed.D.
Chairperson

COMMISSION ON COMPLEMENTARY MEDICAL METHODS

Caril E. Price, Ed.D., Chairperson

Cheryl Diane, B.A.

Gail Geller, Sc.D.

Richard E. Layton, M.D.

Hiroshi Nakazawa, M.D.

Linda M.. Parker, B.A.

Delegate Victor A. Sulin

Jon B. Lowe, M.D., Co-Chairperson

Sidney B. Seidman, M.D.

John F. Strahan, M.D.

Jacob Teitelbaum, M.D.

Edward C. Watters,III, M.D.

Senator Idamae R. Garrett

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Executive Summary

EXECUTIVE SUMMARY

In 1993, the Maryland Legislature created the Maryland Commission on Complementary Medical Methods. Recognizing that complementary medical methods often become standard practice over time, the Legislature believed that individuals should have the right and freedom to choose what they believed to be the most appropriate course of treatment for their medical conditions.

The Commission was charged with: (1) defining which health care methods are complementary; (2) evaluating their costs, benefits, and risks; (3) determining how best to inform patients so that they can make educated choices; and (4) making recommendations on how to make complementary methods available through Maryland physicians.

The Commission has found that complementary methods are often used by Maryland patients and physicians. Unfortunately, physicians are often afraid of discussing complementary methods. This occurs because there is no peer review, and complementary physicians' charts are usually examined by physicians unfamiliar with complementary methods. A survey of the scientific literature shows complementary medicine to be powerful, usually safe, and often inexpensive in promoting citizens' health. Non-peer review may severely limit access to optimum health care for many citizens.

The Commission has gathered data for this study through a combination of qualitative and quantitative methodologies. Through the use of this information,we have defined complementary medical methods as those forms of treatment which are not widely used by conventional health care professionals and the skills of which are not taught as part of the curriculum of conventional medical and paramedical health care courses.

We recommend the following:

1. **We recommend** that current and future physicians be exposed to the range of complementary medical methods available in the State of Maryland. This includes curricular electives in state medical schools and continuing education for practicing physicians.

2. **We recommend** that the guidelines for health insurance coverage be evaluated, and where appropriate, expanded to include coverage for cost-effective complementary medical methods. This would facilitate freedom of choice and promote the integration of allopathic and complementary care for the citizens of the State of Maryland.

3. The Commission believes that if and when the care provided by a physician who practices complementary medicine is subjected to the Board of Physician Quality Assurance (BPQA) scrutiny, BPQA should be required to enlist the expertise of a board certified medical doctor who practices complementary medicine of the same or similar type to perform the review. Therefore, in such cases, the **Commission recommends** that the BPQA contact the National Institute of Health's Office of Alternative Medicine, the American Holistic Medical Association, the Fetzer Foundation, or any other similarly recognized organization or certified board for the names of peer reviewers. BPQA may choose reviewers who are personally unknown to the member being evaluated.

4. As the practice of complementary medical methods by physicians likely represents a small percentage of the complementary medical methods being practiced in the State of Maryland, the **Commission recommends** that the legislature create a funded Commission to explore complementary medical methods used by both physicians and non-physicians practicing in the State of Maryland.

Background/Introduction

INTRODUCTION

The Commission on Complementary Medical Methods was created by the passage of House Bill 382 during the 1993 regular session of the Maryland General Assembly. The act suggested a one year time line for its charge. The Commissioners believed this time limit was unrealistic, and a one year extension was requested of, and granted, by the 1994 Legislature as set forth in Senate Bill 246. Copies of these bills are appended to this report (See Appendix A). These Acts required that a report be presented to the Maryland General Assembly by December 1, 1995. The Commission is especially grateful for the effort and guidance provided by the former Senator from Montgomery County, The Honorable Idamae R. Garrott, who sponsored and introduced the 1994 extension and was exemplary as the Senate representative until her retirement. In the spring of 1993, then- Governor William Donald Schaefer appointed thirteen members and a staff support/liaison from the Department of Health and Mental Hygiene. There were two resignations with appropriate replacement appointments as defined in Appendix B.

On July 1, 1993, House Bill 382 took effect. Recognizing that the practice of medicine has changed over time and continues to evolve with the development of new technology and research, the Bill mandated that a commission on complementary medical methods be established. As noted in the preamble of the Bill, the House recognized that complementary medical methods often become the standard for traditional medicine over time and, feeling that individuals should have the right to freedom to choose what they believe to be the most appropriate course of treatment for their medical conditions, established the above commission. The charges of the Commission were as follows:

1. To define which health care methods are complementary medical methods

2. To evaluate the costs, benefits, and risks associated with the use of complementary medical methods

3. To study how to allow the use of complementary medical methods by Maryland physicians with patients who wish to be treated with complementary methods for their medical conditions

On March 10, 1994, David M. Sale, J.D., LL.M., appeared before the commission. Mr. Sale has been conducting research concerning legislative and related developments affecting complementary health care in the United States with a

supporting grant from the Fetzer Institute. His report endeavored to place the Commission's work in a national context, as noted in Appendix C.

To make complementary medicine available to its citizens, six state legislatures have already passed bills providing legal protection for complementary methods and practitioners (Alaska, Washington, North Carolina, Oklahoma, New York, and Oregon). Several other states are currently considering similar legislation.

Mr. Sale did note that his interpretation of the Bill required that the Commission study how to allow the use of these complementary methods by Maryland physicians. He felt this part of the law was especially significant in relation to the preamble of the Bill which references a person's right and freedom to choose what he/she believes to be the most appropriate course of treatment for the medical condition.

In order to fulfill the mandate of the Commission, several actions were taken. A survey of Maryland physicians was conducted to determine which, if any,complementary medical methods were included in their practices, and evaluate any costs, benefits, and risks associated with the use of these methods. This study was spearheaded by Gail Geller, Sc.D., one of the Commission members.

In addition, a literature review was done to gain an appreciation of the costs, benefits, and risks associated with the use of complementary versus traditional medical methods. To do this, the focus was on modalities practiced by physcians who were members of the Commission ,so that advantage could be taken of their expertise. Jacob Teitelbaum, M.D. (a board-certified internist who serves as the State Medical Society Representative to the Commission and practices traditional medicine combined with nutritional and herbal approaches) was asked to do a review of the large body of scientific literature on nutritional and herbal complementary methods for six diseases. These were chosen because they are well defined diagnoses for which effective treatments are available in both traditional and complementary models. It should be noted that there are many other diagnoses that are effectively treated by both models and there are many other complementary methods that are effective. Dr. Richard E. Layton, M.D. identified a group of physicians who practice a variety of complementary medical modalities available to the citizens of Maryland (See Appendix D for Synopsis).

Definition

DEFINITION OF COMPLEMENTARY MEDICAL METHODS

Many states are beginning to take a close look at the complementary medical methods that are available to their citizens. There are many different definitions to the term. A Bill recently passed by the Oregon House of Representatives by a vote of 56 to 1 (H.B. 3340), defines Complementary Medicine as:

A treatment that the treating physician, based on the physician's professional experience, has an objective basis to believe has a reasonable probability for effectiveness in its intended use, even if the treatment is outside recognized scientific guidelines, is unproven, is no longer used as a generally recognized or standard treatment or lacks the approval of the United States Food and Drug Administration;

A treatment that is supported for specific usages or outcomes by at least one other physician licensed by the Board of Medical examiners; and

A treatment that poses no greater risk in a patient than the generally recognized or standard treatment.

After much review the Commission has decided to adopt the following definition of Complementary Medical Methods:

Those forms of treatment which are not widely used by conventional health care professionals and the skills of which are not taught as part of the curriculum of conventional medical and paramedical health care courses.

Costs, Benefits, and Risks

COSTS, BENEFITS, AND RISKS

After a review of the scientific literature, it has become obvious that there is a large number of complementary medical modalities that contribute to the health and well-being of Maryland patients, and that these modalities are often effective in treating a broad spectrum of illnesses.

Because the Commission has a member whose practice combines traditional methodologies with nutritional and herbal complementary methods, we chose to compare these approaches. It should be noted that many other complementary approaches are likely to be equally or perhaps even more effective. For example, a recent double-blind, placebo- controlled study by Drs. Lao and Berman of the University of Maryland Medical School showed acupuncture to be effective in reducing pain after dental extractions. This study is a model for future control studies of acupuncture's effectiveness.

We also chose to pick six diagnoses that (1) can be clearly defined and (2) have effective treatments by both traditional and complementary modalities (Appendix E). It should be noted that many other illnesses could have been substituted.

What becomes clear after reviewing the data is that orthodox and complementary treatments are not "either/or" choices. Indeed, patients are often helped most by combining these powerful tools. The evidence suggests that physicians who use both modalities can given the ailment, offer their patients a marked decrease in costs and risks and an improvement in health.

Figure 1 is a comparison of orthodox and nutritional/herbal-based treatments for six illnesses:

COMPLEMENTARY					ALLOPATHIC			
Medical Problem	Treatment	Costs (per month)	Effectiveness	Major Side Effects	Treatments	Costs	Effectiveness	Major Side Effects
Osteo-arthritis	Glucosamine 500 mg t.i.d.	$14	95% improved. More effective than Motrin 1200 mg/d	None	NSAIDS-e.g. Motrin, Feldene, etc.	$4.35 to over $90/mo.		Serious hemorrhage, hepatitis, kidney failure, dizziness, confusion.
Disk Disease	IV colchicine weekly for 6 weeks	$280-700	Over 70% showed significant improvement (vs <20% with placebo)	Allergic reactions, skin burns.	Laminectomy	$5,600-7,600		Risk of anesthesia, nerve injury. Increased pain and disability.
Severe Congestive Heart Failure	CoEnzyme Q-10 100 mg/d	$21	Improves patient one functional class	None.	ACE inhibitors Heart transplant	$23-106/mo. $200,000 - 400,000		Hypotension, cough, kidney dysfunction, hyperkalemia Death, stroke, rejection, etc.
Elevated Cholesterol	Garlic 1 gram/d	$3	LDL ~ 15% HDL ~ 10% Trig ~ 15%	None (if deodorized garlic is used).	HMG - CoA reductase inhibitor	$30-125/mo.	Lescol 20 mg/d LDL 19-22% Trig 9% Slight HDL	Hepatitis, myositis
Carpal Tunnel Syndrome	B6 250 mg/d X12 weeks and writst splints	$60	66-98% cure rate	None (neuropathy with excessive dose for years).	Surgery (nerve release)	>$2,700	Good	Nerve injury, anesthetic risk
Benign Prostatic Hypertrophy	Herbal Rx e.g. Serenoa repens 585 mg/d	$2/mo.	~90% of patients improved	None	Surgery (TURP) or Proscar	>$5,000 or $64.58/mo. for Proscar	Good Modest	Impotence, incontinence, anesthetic risk

* Supplemental prices are from Vitamin Shoppe Catalogue (retail)
ǂ Medication costs and side effects and efficacy are from the "Medical Letter" on Drugs and Therapeutics.
Surgical costs are from AAMC Business Office and do not include testing or anesthesiologist fees.

Cost, Benefit and Side Effect Profiles of Complementary and Allopathic Medical Treatment for Six Medical Problems

Figure 1.

Use of Complementary Medical Methods

USE OF COMPLEMENTARY MEDICAL METHODS

Data collection for this study included a combination of qualitative and quantitative research methodologies. The open forum, published solicitation, focus groups ,and mailed survey are described in greater detail below.

Open Forum

Our first method of establishing communication with the citizens of Maryland regarding their attitudes towards complementary medicine involved holding an open forum with the public and the members of the Commission on Complementary Medical Methods (CCMM). The dual purpose of this meeting was to inform the public and be advised by the public about various experiences with complementary medical methods. The forum was held on the evening of March 10, 1994 in Annapolis, Maryland. It was advertized in the *Baltimore Sun*, *the Capitall*, several magazines including *Baltimore Resources* and *Womens' New Age Magazine*, Public Enterprise, the Traditional Acupuncture Institute, various health food stores, and chiropractors' offices. Nineteen individuals testified. Seven were members of the public, seven were non- M.D. providers , and five were M.D. providers. The testimony focused on the benefits of various health care modalities, most of which were under the direction of non-physician providers. After the public testimony, questions were asked of Commission members regarding the purpose of the Commission.

Published Solicitation

In order to assess Maryland physicians' interest in participating in a survey on complementary medical methods, a letter was published in the BPQA (Board of Physician Quality Assurance) newsletter, addressed to all physicians and osteopaths in the State of Maryland. The purpose of our letter was twofold: (1) to explain the mandate of the Commission as defined in House Bill 382 and Senate Bill 246; and (2) to determine the extent to which complementary care was incorporated into physician practices in Maryland. It was important to assess the feasibility of conducting a mailed survey and obtaining a reasonable response rate prior to incurring such an expense, and we thought that those with interest or experience in this area would be more likely to respond. The recepients (of the letter) were requested to contact the Commission if they had practiced ,or were interested in practicing , complementary medicine, and/or if they had "well-established relationships" for referrals to complementary practitioners. In order to allay any concerns about confidentiality that might impede physician response, the Commission assured potential respondents that the information they provided would be kept confidential.

Focus Groups

Two focus groups of physicians were conducted to establish the appropriate content and range of responses for a survey, and to generate hypotheses for analysis (DHHS, 1984). We chose focus groups, as opposed to individual interviews, for several reasons. First, logistically and financially it would have been impossible to interview individual physicians. Bringing them together was more convenient. Second, bringing physicians from different specialties and orientations together allowed for interaction among peers, thereby creating a much richer discussion.

As recommended in the literature on focus group methodology (Morgan, 1992a), the groups were homogeneous in that all participants were physicians in Maryland. We did not want strict control over either the content of the questions or the group dynamics. We decided to develop a minimally structured discussion guide that would allow for flexible interchange among participants.

Recruitment Procedures: Personal invitations (by telephone call from a physician member of the Commission) to participate in a three-hour focus group were extended to a list of physicians that the Commission thought could serve as "key informants". One group was comprised of practitioners of complementary medicine,while the other was comprised of practitioners of conventional medicine. A common purpose of both groups was to inform participants of the following:

a) Goals of the Commission as stated in House Bill 382 and Senate Bill 246

b) Definition of complementary medicine as approved by the Commission

c) Results of the letter published in the BPQA

d) Review of the purpose of qualitative research involving a non-random (purposive) sample

e) Results of David Sale's report and the open forum in Annapolis

In addition, each group had a unique purpose. The meeting of complementary physicians was intended to help us establish the range of items and responses that we would include in a large-scale survey. This meeting took place on June 14, 1994 at the Traditional Acupuncture Institute in Columbia, Maryland. Four practitioners of

complementary medicine who were known to Commission members were invited and agreed to attend. Included were specialists in nutritional medicine and homeopathy. The meeting of conventional practitioners was intended to pre-test the mode of administration and the proposed content of the survey. In order to obtain three-four attendees, over twenty different conventional practitioners were asked to participate. The three participants represented two different specialties (internal medicine and neurosurgery) and orientations, allowing for a stimulating, free-flowing discussion. This focus group took place at the offices of Dr. Richard Layton in Towson, Maryland on September 27, 1994. All participating physicians were practicing in the State of Maryland.

Data Collection and Analysis: The data for the qualitative part of our study came from notes taken of the discussions generated by several structured questions. The questions were devised and posed by several Commission members, using terminology that is well recognized and accepted in the literature on complementary medicine. Two Commission members served as moderators. Minutes of these two focus groups are included in Appendix F.

Mailed Survey

Four hundred eighty- three physicians were selected at random from a pool of physicians who currently practice in Maryland, without regard to specialty. This list was provided by the Board of Physician Quality Assurance.

Procedures: A questionnaire was mailed to all eligible physicians, with a promise that we would not link names and individual responses. We were not able to offer physicians any incentives. However, a letter from the Governor's Commission was included in the mailing (see Appendix G) in the hopes that evidence of a State mandate for this study would motivate physicians to respond.

Analysis: Appendix H provides a summary analysis of outcome variables, predictor variables, and a breakdown of the respondents by demographic characteristics.

RESULTS

Response Rates

In calculating response rates, questionnaires that did not reach the intended respondent because of death, retirement, or relocation were not included in the total count. Two hundred eighty-seven responses were received, for a very respectable response rate of 59.4%. (The average response rate for physicians is 20%). A detailed analysis of differences between respondents and non-respondents is beyond

the scope of this report. However, information on certain demographic and practice characteristics of physicians in the State was made available to us. AMA records as of January 1993 indicate that there are 17,996 non-federal physicians in the State of Maryland. The responses to significant questions are broken down as follows:

Percent of Patients with Whom Physicians Report Discussing Complementary Medicine

Eleven percent (11%) of respondents report discussing complementary medicine with "all" or "most" of their patients. Forty-two percent (42%) discuss it with "less than half" of their patients. Forty-five percent (45%) of respondents report never discussing complementary medicine with their patients.

Attitudes Toward the Appropriateness of Complementary Techniques for Various Conditions

Table I (Appendix H) summarizes respondents' attitudes toward patient use of complementary techniques for nine common conditions. Whereas over half of respondents believe that it is appropriate for patients to try complementary techniques for low back pain, migraines ,and chronic fatigue syndrome, less than one- fourth believe it is appropriate for cancer and otitis media.

Reported Frequency of Referrals for Complementary Medicine

Fifty-four percent (54%) claim never to have recommended complementary medicine to their patients. However, 8% of respondents actually conduct some sort of complementary medicine themselves. Another 8% have recommended complementary medicine to their patients and have provided specific referrals, indicating a familiarity with other complementary practitioners. Thirty percent (30%) have recommended complementary medicine without providing a specific referral. Of the 46% who have recommended complementary medicine to some degree, there are significant differences in the types of modalities that they recommend.

Types of Modalities for Which Referrals Are Reportedly Made

Table II (Appendix H) summarizes respondents' reported referrals for various types of complementary modalities. Biofeedback, chiropractic, nutrition

therapy ,and acupuncture are the most common modalities to which referrals are made. However, fewer than 5% of respondents report referrals for ayurveda, chelation therapy ,or colonic therapy.

Knowledge of Availability of Various Complementary Techniques in One's Geographic Area

Table III (Appendix H) summarizes the degree to which respondents are aware of the availability of various complementary techniques in their owngeographic areas. Whereas over two-thirds of respondents report the availability of chiropractic, acupuncture ,and biofeedback in their geographic area, less than one-fourth report the availability of chelation therapy, neurolinguistic programming, colonic therapy, or ayurveda. However, a large percentage of respondents reported uncertainty about the availability of most of these techniques in their areas.

Physician Characteristics Associated With Likelihood of Discussing and/or Referring for Complementary Medicine

Respondents who indicated that they would discuss complementary medicine with their patients did not differ from other tespondents in these ways: year of graduation from medical school; whether or not they held academic appointments; g ender; or type of geographic area in which they practice. However, those amenable to having such discussions or making such referrals were significantly more likely to have graduated from a U.S. medical school, to have family members who have used complementary medicine, and to report a specialty in internal medicine. We also determined that respondents who reported having made referrals specifically for acupuncture and biofeedback are significantly more likely to practice in suburban areas (vs. urban or rural areas) when compared to respondents who did not report making such referrals. Respondents who reported making referrals for chiropractic are significantly more likely to practice in urban or suburban areas (vs. rural areas) when compared to respondents who did not report making referrals to chiropractors. There were no regional differences in likelihood of making referrals for other types of complementary modalities.

DISCUSSION

Reported Discussions About and Referrals for Complementary Medicine

Given that our survey was limited to a population of physicians, a surprising proportion of respondents reported discussing complementary medicine with their patients to some degree. Similarly, another significant number of respondents report conducting some sort of complementary medicine themselves, or making referrals to specific practitioners who do. However, the patterns of respondents' reported referrals indicate clear preferences for certain types of complementary modalities. Moreover, knowledge of the availability of various modalities parallels the reported frequency of referrals to such modalities. These two findings might indicate clear perceptions about the degree to which certain modalities have become "mainstream". Alternatively, they might merely reflect a "catch-22" where very few complementary techniques are widely known or available, and physicians tend to refer only to practitioners with whom they are familiar.

Attitudes Toward the Appropriateness of Using Complementary Techniques for Various Conditions

Not surprisingly, there is considerable variability in the perceived appropriateness of complementary medicine for specific common conditions. Although this might reflect preconceived notions about the efficacy of such treatments, our data suggest that this finding might reflect typical patterns of referral. For example, respondents commonly report referrals to chiropractors and acupuncturists and tend to be supportive of complementary medicine for the treatment of low back pain. Bivariate analyses indicate a significant relationship between these two variables. Of the 30% of respondents who report having made referrals to chiropractors, 91% have recommended complementary medicine for low back pain. Of the 27% of respondents who report having made referrals to acupuncturists, 83% have recommended complementary medicine for low back pain. Surveys of people in the general population would probably confirm that those who seek complementary medicine for the treatment of low back pain frequently use chiropractic and acupuncture. Similarly, respondents commonly report referrals for biofeedback, and tend to be supportive of complementary medicine for the treatment of migraines. In fact, of the 34% of respondents who report having made referrals for biofeedback, 71% have recommended complementary medicine for migraines. Of the respondents who report having made referrals to acupuncturists, 78% have recommended complementary medicine for migraines. Surveys of people in the general population would probably confirm that those who seek complementary medicine for the

treatment of migraines frequently use acupuncture and biofeedback. However, surveys of people who use complementary medicine are also likely to demonstrate frequent use of acupuncture for the treatment of asthma/allergies and chemical dependency. Yet respondents to our survey who report making referrals for acupuncture are not overwhelmingly supportive of such modalities in the treatment of these specific conditions. Of the 27% of respondents who have made referrals for acupuncture, only 43% would find the use of acupuncture appropriate in the treatment of asthma, and 59% would find it appropriate in the treatment of chemical dependency. Of the 27% of respondents who have made referrals for nutrition therapy, 71% find the use of nutrition therapy appropriate in the treatment of both migraines and irritable bowel syndrome.

Physician Characteristics Associated With Likelihood of Discussing and/or Referring for Complementary Medicine

It is not surprising that the likelihood that respondents would discuss complementary medicine with their patients varied by several characteristics. We had expected that attendance at a foreign medical school would influence the degree to which physicians might incorporate complementary medicine into their practices. However, we hypothesized an association in the opposite direction (i.e., that foreign medical graduates would be more likely to engage in such discussions). Perhaps this finding reflects the desire of foreign medical graduates to assimilate into mainstream American medicine. By contrast, the direction of the associations with specialty and the existence of a family member who uses complementary medicine came as no surprise. The greater likelihood of internists responding to our survey to report discussing complementary medicine compared to other responding specialists may not necessarily reflect a greater acceptance of complementary medicine, but a greater likelihood of seeing patients with conditions for which conventional treatments are thought to be less than successful or have unwanted side effects (e.g., migraines, low back pain, asthma, etc.). The prevalence of reported referrals for acupuncture in suburban areas might reflect the existence of the acupuncture training institute in Columbia, Maryland. Alternately , the prevalence in suburban areas of reported referrals for acupuncture and biofeedback might reflect the tendencies of individuals in upper socioeconomic strata to seek complementary care.

Limitations and Future Research

The validity and generalizability of these results may be affected by several limitations. First, budgetary limitations prevented us from administering the survey to a larger number of physicians. Therefore, our findings may not be representative

of all physicians in Maryland. For example, the fact that internists and family practitioners were more likely to respond, and that internists and family practitioners appear more likely than other specialties to discuss complementary medicine, suggests that we might be overestimating the degree to which physicians in the general population would discuss complementary medicine with their patients. This is an empirical question that warrants prospective study. Moreover, if physicians who responded are more interested in complementary medicine than other physicians, there may have been a tendency to provide socially desirable answers (i.e., what they thought we wanted to hear). This is unlikely, since we demonstrated that our sample is fairly representative of physicians in the State.

Second, this study is limited by the hypothetical nature of the questions. Most physicians have not had formal training in complementary modalities of any kind. If the future demands that physicians have a clear role in referring certain patients for complementary care, some form of training or continuing medical education will be needed to provide them with opportunities to learn about complementary modalities.

Third, a full understanding of the range and availability of complementary modalities in Maryland would require representation of non-physician practitioners. They were not included in our mandate.

Finally, because of limitations of cost, time, and data, the Commission was not able to get a sense of cost or insurance coverage.

Conclusions and Recommendations

CONCLUSIONS AND RECOMMENDATIONS

The Commission's review of the scientific literature in our study has shown that:

1) The public considers complementary medicine to be of great value (e.g. - In 1990 ,sixty-one million Americans made about 425 million visits to complementary practitioners offices).

2) Complementary methods are at times safer, less expensive, and/or more effective than traditional therapies. Both approaches are valuable, and the public interest is best served by having both readily available.

The Commission notes that it is incumbent upon every physician to inform the patient of the benefits, risks, and availability of both complementary and traditional medical methods. *This requirement already exists and is achieved through discussions between the physician and patient. We see no need for further legislation here. If any is proposed, we recommend that it apply equally to allopathic and complementary physicians and modalities.*

Based on the evaluation of our studies and pertinent literature, the Commission **recommends** the following:

I. **WE RECOMMEND** that current and future physicians be exposed to the range of complementary medical methods available in the State of Maryland. This includes curricular electives in state medical schools and continuing education for practicing physicians.

II. **WE RECOMMEND** that the guidelines for health insurance coverage be evaluated and where appropriate, expanded to include coverage for cost-effective complementary medical methods. This would facilitate freedom of choice and promote the integration of allopathic and complementary care for the citizens of the State of Maryland.

III. **WE RECOMMEND** that the Board of Physicians Quality Assurance (BPQA) expand the notion of peer review to include the area of complementary medical methods. This means that if and when the care provided by a physician who practices complementary medicine is subjected to the scrutiny of BPQA, the Board should be required to enlist the expertise of a board certified medical doctor who practices complementary medicine of the same or

similar type to perform the review. Therefore, in such cases, the **COMMISSION RECOMMENDS** that the BPQA contact theOffice of Alternative Medicine at the National Institute of Health , the American Holistic Medical Association, the Fetzer Foundation, or any other similar ly recognized organization or certified board for the names of peer reviewers. BPQA should choose reviewers who are personally unknown to the member being evaluated.

IV. As the practice of complementary medical methods by physicians probably represents a small percentage of the complementary medical methods being practiced in the State of Maryland, the **COMMISSION RECOMMENDS** that the Legislature create a funded Commission to explore complementary medical methods used by both physicians and non-physicians practicing in the State of Maryland.

Medicine in many instances is both science and art. The revered Sir William Osler said it well - "Medicine is a science of uncertainty and an art of probability." The State of Maryland should encourage creativity in medicine that results in good outcomes, prioritizing health,and preventing disease. Integrating conventional and complementary medicine is a positive step in providing optimal medical care to the citizens of Maryland.

We are most grateful to have had the opportunity to serve the Maryland State Legislature and the Citizens of Maryland.

Appendices

Appendices

A. House Bill 382 and Senate Bill 246.

B. Resignations / Replacements

C. Report of David M. Sale, J.D., L.L.M.

D. Modality Definitions

E. Comparison Report

F. Focus Group Minutes

G. Survey with Cover Letter

H. Results of Survey Data

I. Minority Report

HOUSE BILL 382

J2 (3lr1051)

ENROLLED BILL

Introduced by **Delegates Huff, Blumenthal, Dembrow, Sulin, Gary, Cadden, Kolodziejski, Scannello, Valderrama, and Pitkin**

Read and Examined by Proofreaders:

_____
Proofreader.

_____
Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this _____ day of _____ at _____ o'clock, _____M.

_____
Speaker.

CHAPTER_____

AN ACT concerning

Commission on Complementary Medical Methods

FOR the purpose of establishing a Commission on Complementary Medical Methods; providing for the membership of the Commission; charging the Commission with certain duties; requiring the Commission to issue a report and make recommendations by a certain date; providing for the termination of the Commission; and generally relating to the Commission on Complementary Medical Methods.

BY adding to
Article 41 – Governor – Executive and Administrative Departments
Section 18–304
Annotated Code of Maryland
(1990 Replacement Volume and 1992 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.
[Brackets] indicate matter deleted from existing law.
Underlining indicates amendments to bill.
~~Strike-out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.
Italics indicate opposite chamber/conference committee amendments.

Preamble

WHEREAS, The practice of medicine has changed and continues to change with the development of new technology and research; and

WHEREAS, Complementary medical methods often become the standard or traditional practice pattern over time; and

WHEREAS, Individuals should have the right and freedom to choose what they believe to be the most appropriate course of treatment for their medical conditions; now, therefore,

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article 41 – Governor – Executive and Administrative Departments

18–304.

(A) THERE IS A COMMISSION ON COMPLEMENTARY MEDICAL METHODS WHICH SHALL DEFINE WHICH HEALTH CARE METHODS ARE COMPLEMENTARY MEDICAL METHODS AND STUDY HOW TO ALLOW THE USE OF COMPLEMENTARY MEDICAL METHODS BY MARYLAND PHYSICIANS WITH PATIENTS WHO WISH TO BE TREATED THROUGH COMPLEMENTARY METHODS FOR THEIR MEDICAL CONDITIONS.

(B) THE COMMISSION CONSISTS OF THE FOLLOWING MEMBERS:

(1) ~~TWO MEMBERS~~ *ONE MEMBER* OF THE HOUSE OF DELEGATES, APPOINTED BY THE SPEAKER OF THE HOUSE;

(2) ~~TWO MEMBERS~~ *ONE MEMBER* OF THE SENATE OF MARYLAND, APPOINTED BY THE PRESIDENT OF THE SENATE; AND

(3) ~~TEN~~ *ELEVEN* MEMBERS APPOINTED BY THE GOVERNOR, AS FOLLOWS:

(I) THE SECRETARY OF HEALTH AND MENTAL HYGIENE, OR THE SECRETARY'S DESIGNEE;

(II) TWO MEMBERS REPRESENTING THE BOARD OF PHYSICIAN QUALITY ASSURANCE;

(III) TWO MEMBERS REPRESENTING THE MEDICAL AND CHIRURGICAL FACULTY OF MARYLAND;

(IV) ONE MARYLAND PHYSICIAN WITH EXPERTISE IN THE USE OF COMPLEMENTARY MEDICAL METHODS;

(V) ONE MEMBER REPRESENTING HOSPITALS IN MARYLAND

~~(V)~~ *(VI)* TWO PATIENTS OR FORMER PATIENTS OF PHYSICIANS WHO TREAT PATIENTS WITH COMPLEMENTARY MEDICAL METHODS; AND

~~(VI)~~ *(VII)* TWO MEMBERS OF THE GENERAL PUBLIC.

(C) THE COMMISSION IS CHARGED WITH:

(1) DEFINING WHICH HEALTH CARE METHODS ARE COMPLEMENTARY MEDICAL METHODS *BEING USED BY PHYSICIANS IN MARYLAND;*

~~(1)~~ ~~(2) DETERMINING WHAT KIND OF COMPLEMENTARY MEDICAL METHODS ARE BEING USED BY PHYSICIANS IN MARYLAND;~~

~~(2)~~ ~~(3)~~ *(2)* EVALUATING THE COSTS, BENEFITS, AND RISKS ASSOCIATED WITH THE USE OF COMPLEMENTARY MEDICAL METHODS;

~~(3)~~ ~~(4)~~ *(3)* DETERMINING HOW BEST TO INFORM PATIENTS OF THE BENEFITS AND RISKS ASSOCIATED WITH THE USE OF COMPLEMENTARY MEDICAL METHODS *AND THE AVAILABILITY OF OTHER METHODS OF TREATMENT*; AND

~~(4)~~ ~~(5)~~ *(4)* REPORTING RECOMMENDATIONS ON COMPLEMENTARY MEDICAL METHODS IN ACCORDANCE WITH THIS SECTION.

(D) THE MEMBERS OF THE COMMISSION SHALL SELECT A CHAIRPERSON FROM THE MEMBERSHIP OF THE COMMISSION.

(E) MEMBERS OF THE COMMISSION SHALL SERVE WITHOUT COMPENSATION.

(F) THE COMMISSION SHALL REPORT ITS FINDINGS AND RECOMMENDATIONS TO THE GOVERNOR AND, SUBJECT TO § 2-1312 OF THE STATE GOVERNMENT ARTICLE, TO THE GENERAL ASSEMBLY BY ~~JULY~~ DECEMBER 1, 1994 AND THEREAFTER TERMINATE ITS EXISTENCE.

(G) STAFF FOR THE COMMISSION SHALL BE PROVIDED BY THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect ~~October~~ July 1, 1993.

Approved:

_____

Governor.

_____

Speaker of the House of Delegates.

_____

President of the Senate.

SENATE BILL 246

J1 4lr133

By: **Senator Garrott**
Introduced and read first time: January 20, 1994
Assigned to: Economic and Environmental Affairs

A BILL ENTITLED

AN ACT concerning

Commission on Complementary Medical Methods

FOR *the purpose of extending the deadline for the Commission on Complementary* Medical Methods to issue a report and make recommendations; extending the termination date of the Commission; and generally relating to the Commission on Complementary Medical Methods.

BY repealing and reenacting, without amendments,
Article 41 – Governor – Executive and Administrative Departments
Section 18–305(a)
Annotated Code of Maryland
(1993 Replacement Volume)

BY repealing and reenacting, with amendments,
Article 41 – Governor – Executive and Administrative Departments
Section 18–305(f)
Annotated Code of Maryland
(1993 Replacement Volume)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article 41 – Governor – Executive and Administrative Departments

18–305.

(a) There is a Commission on Complementary Medical Methods which shall define which health care methods are complementary medical methods and study how to allow the use of complementary medical methods by Maryland physicians and other health care providers with patients who wish to be treated through complementary methods for their medical conditions.

(f) The Commission shall report its findings and recommendations to the Governor and, subject to § 2–1312 of the State Government Article, to the General Assembly by December 1, [1994] 1995 and thereafter terminate its existence.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.
[Brackets] indicate matter deleted from existing law.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 1994.

Appendix B

Resignations / Replacements

Resigned Commission Members

Brian Martin Berman, M.D.	-	Medical and Chirurgical Faculty of Maryland
William Tham, M.D.	-	Medical and Chirurgical Faculty of Maryland

Replacement Commission Members

Hiroshi Nakazawa, M.D.	-	Medical and Chirurgical Faculty of Maryland
Jacob Teitelbaum, M.D.	-	Medical and Chirurgical Faculty of Maryland

Appendix C

STATEMENT OF DAVID M. SALE, J.D., LL.M.

before

THE MARYLAND COMMISSION ON COMPLEMENTARY MEDICAL METHODS

March 10, 1994

Office: (410) 841-3870
Fax: (410) 841-3850

CONTENTS

STATEMENT OF DAVID M. SALE, J.D., LL.M., before the MARYLAND COMMISSION ON COMPLEMENTARY MEDICAL METHODS

March 10, 1994

Mr. Chairman and members of the Commission, it is a pleasure to be with you today to consider some of the important and groundbreaking issues that the Commission will be addressing this year and perhaps in 1995 concerning the use of complementary medical methods by Maryland physicians.

My name is David Sale and I am here at the request of the Commission and with the consent of my agency, the Maryland Department of Legislative Reference. That which I will say, however, should in no way be construed to reflect the views of the Department of Legislative Reference. I appear, therefore, solely in a private capacity as an attorney who is interested in fostering the responsible development of this field and in assisting the Commission in its work.

With a supporting grant from the John E. Fetzer Institute, located in Kalamazoo, Michigan, I began last year to perform research concerning legislative and related developments affecting complementary health care in the United States. The Fetzer Institute is a nonprofit educational organization active in sponsoring mind-body research and currently funds programs for this purpose at a number of leading American universities. The Institute also sponsored the acclaimed PBS television series last year entitled "Healing and the Mind," which was hosted by Bill Moyers. What I would like to present to the Commission today draws in part upon my research to date under the Fetzer grant, with an emphasis on that portion of the project which appears to be most relevant to the work of the Commission.

My statement is intended (1) to place the Commission's work in a national context by reference to a number of significant recent trends in the United States, (2) to discuss emerging legislative developments in other states and in Maryland that appear to bear directly on the Commission's task, (3) to touch upon the scope of the Commission's statutory mandate, and (4) to suggest some legislative issues for the Commission's consideration.

National Context

It is my view and that of many others that a fundamental shift is underway in American society at this time concerning the operative paradigms of health care. The existing allopathic model of health care treatment is beginning to accommodate a popular and, to an increasing degree, professional demand for more holistic or "complementary" means of care. Under the complementary approach to health care, practitioners and their patients or clients tend to view health care in a healing context that extends beyond physical well-being to include an equal, and often indispensable, concern for personal emotional, mental, and even spiritual health.

Given the current national impetus toward a more holistic model of care, it is reasonable to expect that consumer, political, legal, scientific, and medical communities in this country will pay increased attention to the complementary health care paradigm in the remaining years of this decade and well into the next century. Indeed, the Twenty-First Century may bear witness to a dramatic and functional *rapprochement* between allopathic and complementary models of care that synthesizes the best from each mode of treatment.

There are four recent trends involving the complementary health care arena that reveal the likely contours of future developments in this field and provide the relevant national context for the work of this Commission. These trends function in a synergistic relationship in which activity in one area impacts or generates associated activity in another, thereby intensifying overall movement toward a new understanding and accommodation of a more holistic or complementary approach to health care.

1. Consumer Demand

As indicated in a study published in the *New England Journal of Medicine* (January 28, 1993), the use of complementary therapy is widespread in the United States with some 61 million Americans making about 425 million visits to complementary practitioners in 1990. According to the study, this number exceeded the number of visits to all primary care physicians in this country. Consumers spent approximately $13.7 billion in 1990 on complementary therapies and paid three-quarters of this amount ($10.3 billion) out of their own pockets. Moreover, the use of complementary therapies was not limited to a narrow segment of American society, but ranged from 23 to 53 percent in all sociodemographic groups considered by the study. There appears to be no reason to doubt, and every reason to believe, that the use of these therapies has not subsided since 1990 and will only increase in the years ahead.

2. Scientific Research

In the scientific field, the recent establishment of the Office of Alternative Medicine (OAM) at the National Institutes of Health not only evidences some shifting in the operative paradigm of health care, but also substantially enhances the threshold credibility of scientific research into complementary modalities. Under its authorizing statute, OAM is charged with facilitating the evaluation of alternative medical treatments, including acupuncture and Oriental medicine, homeopathic medicine, and physical manipulation therapies. OAM is also required by statute to establish an information clearinghouse to exchange information with the public about alternative medicine and to support research training in this field.

In November of 1993, OAM made an initial award of 30 grants for scientific research involving a variety of complementary health care modalities. A list of these initial grants appears in Appendix A to this Statement.

In Maryland, the Commission is undoubtedly aware of the work of Dr. Brian Berman, a member of this Commission, at the University of Maryland Multidisciplinary Pain Center concerning the efficacy of various complementary modalities in treating patients with chronic pain and stress.

3. Increase in Number of Complementary Practitioners

Both inside and outside the established medical community, there exists a growing network of practitioners who provide or recommend complementary treatments for specific illnesses and for the general maintenance of health and well-being. These practitioners provide a wide assortment of treatments to an increasingly enthusiastic, curious, and in some instances, medically desperate or exasperated public.

Although, as previously indicated, millions of Americans utilize complementary means of care, these modalities are not part of the official legal and medical consensus of what constitutes acceptable treatment. In the United States, concern about professional ostracism and adverse legal action by state and federal agencies may inhibit the open practice of complementary treatments by medical and nonmedical practitioners, limit access by the public to many helpful and potentially curative treatments, and generally chill the climate for the responsible and progressive development of the complementary health care field.

In the coming years, the need to accommodate the professional interests of the increasing number of complementary practitioners will likely become acute. At the same time, public and professional interest will remain high in ensuring proper credentialing of these practitioners and in preserving reasonable jurisdiction in the State to protect the health and safety of health consumers.

4. Legislative Developments

The legislative arena has not been immune to pressure by health consumers and practitioners to provide a greater degree of accommodation for access to, and the practice of, complementary means of care. At the state level, the emerging legislative response is reflected in two broad categories of enactments: (1) laws regulating the practice of specific complementary modalities, such as acupuncture, homeopathy, naturopathy, reflexology, and massage and related forms of bodywork, and (2) amendments to medical practice acts that authorize physicians under certain circumstances to utilize complementary modalities.

While the second of these two categories seems most directly relevant to the Commission's work, it is worth noting contextually that acupuncture is now authorized by statute in some 27 jurisdictions, with three states adopting new acupuncture practice acts in 1993; massage practice acts are in place in 19 states, with nearly one-third of these laws having been enacted since 1991; homeopathy practice acts exist in 3 states; naturopathy practice acts are found in 7 states; and one state has established an independent board of reflexology.

Increasingly, state laws and regulations are referring to a variety of lesser known complementary modalities in defining the scope of practice for two of the more prominently regulated complementary therapies--acupuncture and massage. For example, the Maine massage practice act specifically excludes such complementary modalities as rolfing, trager, reflexology, shiatsu, reiki, and polarity. On the other hand, the Delaware Massage/Bodywork law, which establishes a composite administrative committee of massage and allied bodywork practitioners, establishes a certification program authorizing participation by practitioners of alexander technique, therapeutic technique, feldenkrais, hellerwork, oriental bodywork, rolfing, trager, bioenergetics, and shiatsu. The very existence of statutory references to these somewhat obscure complementary modalities is a new development and indicates that the practice and access interests of a growing number of complementary practitioners and patients and clients are already forming part of state legislative and regulatory agenda.

Medical Practice Act Legislation

As previously indicated, the second broad category of current legislative developments seems most relevant to the Commission's immediate task. This category consists of provisions in state medical practice acts which, under certain circumstances, moderate the disciplinary authority of a state medical board concerning a physician who practices a complementary modality. The Commission may wish to consider these legislative developments carefully, particularly for purposes of any legislative recommendations it makes in its final report to the Governor and General Assembly.

For purposes of the succeeding analysis, reference may be made to Appendix B of this Statement, which reproduces the texts of relevant state laws and unenacted legislation.

1. Alaska

The first modern medical practice statute to accommodate complementary physicians was enacted in 1990 in Alaska and provides that the state medical board "may not base a finding of professional incompetence solely on the basis that a licensee's practice is unconventional or experimental in the absence of demonstrable physical harm to a patient." Under this provision, a showing of actual physical harm to a patient would seem necessary to support a finding of professional incompetence, regardless of the degree of intrinsic risk that a particular form of treatment might pose for a patient before actual treatment.

2. Washington

In 1991, the state of Washington adopted a measure specifying that "the use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed." Compared to the Alaska law, the Washington statute accords the state medical board greater administrative leeway in disciplining a complementary

physician. This is true because the Washington legislation adds a reference to the "unreasonable risk that a patient may be harmed" by an unconventional mode of treatment. The relevance of risk assessment under the Washington law suggests that, even in the absence of actual physical harm to a patient, the medical board in that state could take disciplinary action against a complementary physician for professional misconduct.

The experience of the Washington medical board has not been substantial under the 1991 law. Although the statute intentionally has made it more difficult for the Board to take disciplinary action against licensees, the Board advises that it has not hesitated to charge and investigate complementary physicians.

3. North Carolina

In 1993, North Carolina enacted a statute that keys the disciplinary authority of the state medical board explicitly to either (1) a comparison involving the relative safety of utilizing a complementary versus an allopathic form of treatment, or (2) an evaluation of the relative effectiveness of the complementary form of treatment itself. The law provides that:

> The Board shall not revoke the license of or deny a license to a person solely because of that person's practice of a therapy that is experimental, nontraditional, or that departs from acceptable and prevailing medical practices unless, by competent evidence the Board can establish that the treatment has a safety risk greater than the prevailing treatment or that the treatment is generally not effective.

Unlike the laws in Alaska and Washington, which clearly focus on actual or potential harm to the *patient*, the North Carolina statute makes no direct reference to the interests of the patient, but imports a somewhat more abstract standard involving either (1) the effectiveness of the complementary treatment as such, or (2) a comparative assessment of its risk relative to a conventional prevailing treatment. In an actual case, it is possible that the comparative safety and effectiveness evaluations mandated by the North Carolina law may authorize the admission of a broader range of scientific and clinical evidence than would otherwise be possible under a statutory test that focuses solely on actual or potential harm to a specific patient.

Legal counsel for the North Carolina medical board indicates that the new law has changed the board's disciplinary practices and raised the burden of proof needed to take administrative action. The law has not, however, impaired the ability of the board to take disciplinary action in cases involving outright incompetency.

4. Florida

Companion House and Senate bills were introduced in the Florida legislature in 1993 that would have prohibited the state medical board from taking any action against a physician for the use of a nontraditional treatment, if the treatment does not injure the patient or create an unreasonable risk of harm. These bills, which did not pass, are similar in terms and apparent legal effect to the Washington statute.

5. New York

The New York legislature is presently considering a bill to limit the authority of the state medical board to discipline physicians who use complementary therapies. Compared to kindred enactments in other states, the legislation in New York represents the most detailed approach to date in authorizing a physician to administer complementary health care treatments. The bill parallels the laws in Alaska, Washington, and North Carolina in limiting the authority of the state medical board to take disciplinary action solely on the ground that the licensee's practice includes an alternative medical treatment. Apart from this similarity, however, the proposal departs substantially from these other statutes in its provisions for informed consent and in its formal definition of "alternative medical treatment."

Informed Consent. Under the New York bill, a physician who uses an alternative medical treatment must obtain the written, informed consent of the patient after having disclosed to the patient that the particular alternative treatment is "alternative." The physician must also disclose "conventional options" and the reasonable risks and benefits of treatment in a manner that allows the patient to make a knowledgeable evaluation. None of the previously mentioned state legislation contains such detailed requirements concerning the informed consent of the patient.

Definition of "Alternative Medical Treatment." The New York legislation also differs from that adopted or proposed in other states by actually defining "alternative medical treatment." This type of treatment is deemed to involve a modality that is not recognized by a specialty board member of the American board of medical specialities, but which is:

(1) a treatment that uses therapeutic agents listed in the United States pharmacopoeia, United States homeopathic pharmacopoeia, or the national formulary;

(2) a treatment that has been demonstrated to exert a favorable influence in similar conditions, as evidenced by a substantial body of medical literature or through professional conferences sponsored by medical societies, hospitals, accredited medical colleges or academies, not-for-profit associations incorporated for the advancement of medical science, or federal health institutes; or

(3) a treatment undertaken in participation with an experimental study approved by the National Institutes of Health (NIH) or by an institutional review board under the authority of the federal Food and Drug Administration (FDA), and conducted under generally accepted protocols for medical research, including outcome based studies.

In view of the pharmacological, medical, and institutional references in the bill's definition of "alternative medical treatment," the medical and scientific perspective of this Commission would be helpful in determining what complementary modalities the bill actually authorizes a complementary physician to utilize. The related legal/policy issue is to what extent does the need for official approval, which is implicit in the bill's scientific and institutional references, permit or restrict the practice of a reasonable range of complementary therapies by a physician.

6. Maryland

During three legislative sessions from 1991-1993, complementary legislation that endeavored to follow the lead of Alaska and Washington failed to pass the Maryland General Assembly.

The most recent version of this legislation in 1993 would have prohibited disciplinary action by the state medical board against a physician "solely because the licensee uses a complementary medical method." The proposed limitation on the board's authority would have applied if the physician (1) documented the patient's informed consent for the use of the complementary medical method in the patient's medical record, and (2) complied with recognized standards of medical practice. This latter condition is facially inconsistent with the basic intent of the bill, inasmuch as complementary medical methods are generally understood not to conform to "recognized standards of medical practice."

The 1992 legislation was identical to the 1993 bill, except that the 1992 version used the words "nontraditional medical methods" instead of "complementary medical method." The preferred terminology is probably "complementary medical method," inasmuch this phraseology suggests the existence of an accommodation with allopathic models of care, avoids the separatist implications of the designation "alternative" medical method, and further avoids the anomaly of labelling a method "nontraditional" when it may actually predate an allopathic method in time. Another useful descriptive term might be "non-conventional," which includes both complementary therapies and treatments that are truly non-complementary or "alternative" to allopathic therapies.

The 1991 legislation essentially followed the Alaska model and would have required a showing of demonstrable physical harm to a patient before the medical board could take disciplinary action against a physician licensee. The 1991 bill also would have required the Board of Physician Quality Assurance to develop a model informed consent form for use by a physician whose practice is in whole or in part unconventional or experimental.

The Statutory Mandate of the Commission

1. Scope of the Commission's Charge

It is a fundamental principle of statutory interpretation that legislation must be read as a whole. In applying this legal standard to the law establishing the Commission, it appears that the Commission's legislative charge has two interrelated parts.

The first part is essentially oriented toward the collection, categorization, and evaluation of complementary data, coupled with an obligation to devise a meaningful informational procedure about complementary and other forms of care for the benefit of patients. This aspect of the Commission's statute is reflected in Article 41, § 18-305(c)(1) through (3) of the Code.

The second part of the Commission's charge is found in § 18-305(a) of the law and is more proactive in focus. This provision requires the Commission to study "how to allow" the use of complementary medical methods by Maryland physicians with patients who wish to be treated by these methods. This portion of the law becomes even more significant in relation to: (1) the Preamble of the bill, which references a person's right and freedom to choose what they believe to be the most appropriate course of treatment for their medical conditions, and (2) the Commission's reporting obligation under § 18-305(c)(4) which, in requiring the Commission to report its recommendations in accordance with the entire section, would include *a fortiori* the proactive mandate of subsection (a).

2. Overlapping Charge with the Maryland Health Care Access and Cost Commission

Under the 1993 law establishing the Maryland Health Care Access and Cost Commission (MHCACC), that Commission is charged with establishing and developing a medical care data base on health care services rendered by health care practitioners in the State. The staff of the MHCACC advises that, on January 6 of this year, the Commission approved a staff recommendation that identified the specific categories of providers from whom the MHCACC initially will obtain medical care data.

There are only three provider groups in the MHCACC's list, however, that reasonably may be viewed as providing some form of complementary care--chiropractors, osteopaths and, to some unknown extent, physicians. Of these three provider groups, data relating to the complementary practices of physicians and presumably osteopathic physicians would be covered by the current charge of the Maryland Commission on Complementary Medical Methods, but chiropractic data technically would not applicable, unless a chiropractor is deemed to be a "physician" for purposes of this Commission's statutory mandate.

It is my further understanding that, pending the establishment of an electronic data base this year through an RFP, the MHCACC will not obtain medical practice data directly from providers in 1994, but indirectly from insurance carriers. This suggests that, for purposes of the mandate of the Maryland Commission on Complementary Medical Methods, some piggyback data theoretically might be obtained from the MHCACC this year concerning osteopathic and physician practices, but only to the extent that claims data for osteopathic and physician services actually reflect reimbursable complementary practices. In the case of physician services, it seems doubtful that many, if any, claims for complementary services will be filed with carriers.

3. Status of Complementary Providers Under Maryland Law

At its first meeting on December 10, 1993, the Maryland Commission on Complementary Medical Methods approved a recommendation to seek legislation in 1994 to extend the life of the Commission for an additional year and to expand its charge to include the nonphysician category. Subsequently, on January 20, Senator Garrott introduced Senate Bill 246, which would allow the Commission to submit its final report in December, 1995, and to include "other health care providers" apart from physicians in its statutory charge. It is my understanding that, at the request of the Commission, the bill will be amended to exclude reference to "other health care providers" and to confine the Commission's mandate to complementary methods used by *physicians* only.

While the question whether to include or exclude within its statutory charge complementary providers who are not physicians is a policy issue for the Commission and the General Assembly, for informational purposes the Commission may wish to know what status complementary providers currently have under Maryland law. In this regard, it is useful to consider the following four categories of providers:

(1) Allopathic or conventional providers licensed under the Health Occupations Article who, in actual practice, may utilize one or more complementary modalities (*e.g.*, a physician who uses acupuncture or homeopathic remedies, a dentist who uses acupuncture, or a physical therapist who uses massage). The validity of the use of a complementary modality by these currently licensed providers depends principally on the statutory scope of practice for the particular profession.

(2) Complementary health care providers who are licensed or registered under the Health Occupations Article and whose practices are by definition based exclusively or substantially on the use of a complementary modality (*e.g.*, registered acupuncturists and licensed osteopaths and chiropractors). As the law specifically authorizes these complementary providers to practice a particular complementary modality, the right to practice the modality as such is not a legal issue.

(3) Complementary health care providers who are specifically exempt from regulation under the Medical Practice Act and, in effect, from the Health Occupations Article generally (*e.g.*, persons who perform massage by hand and by no other means and Christian Science practitioners). The recent court case involving massage providers and physical therapists does not question the right of massage providers to practice massage *per se*, but only their right to practice and advertise "therapeutic" massage, which the physical therapists contend is within the scope of practice for physical therapy.

(4) Myriad numbers of other complementary health care providers whose legal status is not explicitly addressed under current statutory law (*e.g.*, homeopaths, naturopaths, iridologists, aromatherapists, Bach flower therapists, energy field practitioners, practitioners of spiritual healing modalities other than Christian Science, and many types of body workers, such as practitioners of rolfing, trager, reflexology, shiatsu, polarity therapy, feldenkrais, hellerwork, therapeutic touch, oriental bodywork, acupressure, and alexander technique, to mention only a few of these modalities). Technically, practitioners who use these modalities are engaged in the unlicensed practice of medicine owing to the all inclusive nature of the definition of "practice medicine" under § 14-101(k) of the Health Occupations Article in Maryland and under similar definitions in the medical practice acts of virtually every state. On the other hand, the widespread practice and use of these modalities throughout the United States (and to some unknown extent in Maryland) illustrates the contemporary gap between existing law and the social reality of burgeoning resort to complementary health care treatments in this country.

Legislative Issues under the Commission's Current Mandate

1. Qualified Authorization for Physicians to Use Complementary Methods

Based on what has already been indicated about the laws in Alaska, Washington, and North Carolina, as well as the pending legislation in New York and prior bills in Maryland, the Commission has various legislative models to which it may refer for purposes of authorizing Maryland physicians to use complementary methods. Although efforts to amend Maryland law along these lines have not been successful in recent years, timing and the formal recommendation of this official governmental commission may be significant positive factors. With regard to timing, it is interesting to note that a bill to establish this Commission failed in 1992, but passed overwhelmingly in 1993.

In light of the Commission's proactive mandate, perhaps the key legal/policy issue for the Commission in drawing upon laws in other states, or in developing a model of its own, lies in formulating legislative language that accommodates (1) the State's long-standing interest in protecting the health and safety of its citizens with (2) the newly emerging State interest, as expressed in the Preamble to the law establishing the Commission, in ensuring individuals their "right and freedom to choose what they believe to be the most appropriate course of treatment for their medical conditions."

2. Authorizations for Physicians to Participate in Multidisciplinary Health Care Teams

As allopathic and complementary health care providers increasingly come to appreciate the contribution each can make to the common ideal of healing, the health care of the future will likely involve greater utilization of multidisciplinary teams composed of physicians and a broad range of complementary practitioners. If the Commission decides to encourage a multidisciplinary approach to health care along these lines, it may wish to examine Maryland laws that inhibit physicians and many complementary providers from practicing in this type of setting.

In this regard, reference may be made to § 14-404(a)(18) of the Health Occupations Article, which prohibits a physician from "practic[ing] medicine with an unauthorized person or aid[ing] an unauthorized person in the practice of medicine." Under this provision and particularly in light of the all encompassing definition of "practice medicine" under state law, a physician who practices jointly with a complementary provider would be subject to disciplinary action by the medical board if the complementary provider: (1) is not otherwise authorized to practice under another provider practice act, or (2) does not qualify for the exemptions in the medical practice act for Christian Scientist practitioners or for persons who perform massage by hand and by no other means.

The possibility of disciplinary action is exacerbated by the broad definition of "practice medicine" under Maryland law. Specifically, §§ 14-101(k) and 14-102 of the State medical practice act effectively prohibit anyone who is not otherwise regulated or exempted under the Health Occupations Article from "healing [or] treating. . .any physical, mental, or emotional ailment. . .of an individual. . .by physical, mental, emotional, or other process that is exercised or invoked by the practitioner, patient, or both." Accordingly, if a physician participates in a multidisciplinary clinical practice with, for example, a nonphysician homeopath, a naturopath, a rolfer, and an energy field practitioner, the physician technically would be in violation of § 14-404(a)(18) for practicing medicine with an unauthorized person or aiding an unauthorized person to practice medicine and the other providers would be engaged in the unauthorized practice of medicine under § 14-101(k).

The definition of "practice medicine" in § 14-101(k), which is similar to that in many other states, is facially so broad that a husband technically would be unlawfully practicing medicine if he "treat[ed]" his wife for the "physical. . .ailment" of a headache by giving her an aspirin. The absurdity of applying the law in this instance has led a number of states to put exceptions in their medical practice acts to ensure that all-encompassing statutory definitions of "practice medicine" do not apply to treatments administered by one family member to another.

For purposes of the Commission's present mandate, therefore, one question might be whether the language of §§ 14-101(k) and 14-404(a)(18) is overly broad and potentially inimical to the development of multidisciplinary clinical associations between Maryland physicians and currently unregulated complementary practitioners.

Pilot Project. As an alternative to a permanent amendment to this statutory language, the Commission may wish to consider recommending the establishment of a pilot project in which complementary and allopathic providers provide a range of health care services in a multidisciplinary clinical setting under a protocol that facilitates the initial administration of the least costly, most non-invasive form of treatment. Through a specific legislative exemption from the previously cited statutes, the technical legal barriers under current law to clinical cooperation in this form could be temporarily lifted for the life of the project.

In this way, a participating physician would not be deemed in violation of § 14-404(a)(18) and a participating complementary practitioner, who is not already licensed, registered, or exempted from regulation under State law, would not be deemed to be in violation of § 14-101(k) of the Medical Practice Act. The political and social viability of such a project would seem to be enhanced where funding is provided with support from private foundations that are presently active in the complementary field and where the health care services are offered to persons whose access to health care is limited or nonexistent.

3. Complementary Medical Representation on the Medical Board

Another issue the Commission might wish to consider is whether to have a complementary physician on the state medical board. A legislative effort to do this was made in 1992, but was not successful. A bill has been introduced this session (H.B. 166/Delegate Workman) to place an osteopathic physician on the board, but was given an unfavorable report by the House Environmental Matters Committee. Currently, among the states that accommodate complementary physicians by statute, Alaska has a complementary physician on its state medical board and Washington expects to have a complementary physician in the future.

It is my understanding that issues relating to the composition of the state medical board have also been raised during the recent hearings on the New York bill which, as previously indicated, would grant physicians the qualified right to practice complementary methods. In New York, proponents of this legislation have argued that fundamental fairness requires the presence of a complementary peer on an administrative board that would exercise disciplinary authority over a physician who uses these methods of treatment.

An alternative to having a complementary physician on the medical board would be to ensure the presence of such a physician on the board during disciplinary proceedings against a complementary defendant. Analogously, under § 14-401(b)(2)(i) of the Health Occupations Article, investigative referrals by the Board to MEDCHI in standard of care cases must involve physician peer review "within the involved medical specialty."

4. Medical Education Concerning the Complementary Paradigm

In making its legislative recommendations to enable physicians to practice complementary medicine, it would be natural for the Commission to make appropriate recommendations for medical students and currently licensed physicians to learn more about the emerging complementary health care paradigm. In this regard, the Commission may wish to obtain detailed information about programs of this nature that are currently operating at medical schools at Harvard, Georgetown, and elsewhere. Given the extensive use by American consumers of complementary modalities, as reported in the *New England Journal of Medicine* last year, and the unwillingness of many of these consumers to inform their physicians about the use of these therapies, the Commission may even wish to consider adopting some form of a continuing education requirement to heighten physician exposure to this field.

Conclusion

In addition to the information which I have presented today, the Commission may also want to consider the practice of other countries in this field, particularly English practice. A comparison of legislation and actual practice in the United States with that extant in other western democracies may yield fruitful new approaches toward a reasonable accommodation of complementary medicine in this country.

To this end, the Commission may wish to explore the possibility of obtaining the assistance of two units of the National Institutes of Health--the Office of Alternative Medicine and the Fogarty International Center. The Foreign Law Division of the Law Library of the Library of Congress may also be helpful in identifying relevant laws in other nations. In addition, at the Commission's request, I would be happy to make an independent inquiry through various contacts of my own to obtain relevant foreign materials.

I would also like to leave with the Commission a copy of three significant studies that have been done in this field. These studies were somewhat more broadly based than the scope of the Commission's current mandate, but will assist the Commission in formulating the overall complementary health care context within which it may faithfully implement its own charge. The studies are as follows:

(1) Board of Medical Quality Assurance (California), *Proposal for Revision of Section 2052 of the Medical Practice Act* (November 1, 1982);

(2) L. Andrews, *Deregulating Doctoring: Do Medical Licensing Laws Meet Today's Health Care Needs?* (1983) (People's Medical Society); and

(3) Legislative Research Commission, *Alternative Medical Practices--Report to the 1993 General Assembly of North Carolina* (January 15, 1993).

I appreciate the opportunity to be with you today and I hope that this information will be helpful to the Commission in the discharge of its important mandate. Subject to the further approval of my agency, I would be delighted to assist the Commission in any way.

Appendix A

LIST OF INITIAL GRANTS AWARDED BY THE NIH OFFICE OF ALTERNATIVE MEDICINE

*Mary Banks Jasnoski, George Washington University:

Can **visualization exercises** and **progressive muscle relaxation** boost the immune system?

*Scott R. Walker, University of New Mexico:

Can **prayers** by loved ones help a person recover from problems relating to drug abuse, and might those prayers gradually affect the person's religious or spiritual orientation?

*David Shannahoff-Khalsa, Foundation for Medical Science, Delmar, California:

Can a **yogic breathing technique** performed one hour per day reduce the symptoms of obsessive compulsive disorder?

*Kedar N. Prasad, University of Colorado Health Sciences Center:

Can high doses of **antioxidant vitamins** enhance the ability of anti-cancer drugs to kill tumor cells? (Test tube experiment only).

*John J. Allen, University of Arizona:

Can **acupuncture** help in the treatment of severe depression in women, and is the Chinese medicine-based diagnosis of "disharmony" comparable to a conventional diagnosis of depression?

*Helen Joan Crawford, Virginia Polytechnic Institute and State University:

Can **hypnosis** reduce suffering from chronic low back pain, and how does it affect the electrophysiology of brain regions involved in pain perception?

*C.K. Chou, City of Hope National Medical Center, Duarte, California:

Can passage of a direct electrical current into the body (**"electrochemical treatment"**) widely used in China, shrink tumors or boost the immune system? (Experiments on cultured cells only).

*Richard A. Sherman, Fitzsimmons Army Medical Center, Aurora, Colorado:

Can **biofeedback** help control low back pain or pain in the face and jaw?

*Carol Ginandes, McLean Hospital, Belmont, Massachusetts:

Can **hypnosis** accelerate bone healing in people with fractured ankles?

*Angela V. McGrady, Medical College of Ohio, Toledo, Ohio:

Can **biofeedback-assisted relaxation** reduce the need for insulin in people with type I diabetes?

*D. Blair Justice, University of Texas Health Sciences Center:

Can **imagery and relaxation techniques** improve quality of life and immune function in women who have completed treatment for breast cancer?

*James P. Halper, Lenox Hill Hospital, New York:

Can **guided imagery** reduce symptoms and the need for medication, and improve airway function, in asthma patients?

*Martin H. Krag, University of Vermont:

Can force detectors and infrared cameras measure the precise forces involved in **chiropractic** manipulations and show how those forces affect the spine?

*Thomas J. Birk, Morse Physical Health Research Center, Toledo, Ohio:

Can **massage therapy** improve immune function when used in combination with antiviral drugs in patients with advanced AIDS?

*Denise Matt Tope, Dartmouth College, Hanover, N.H.:

Can **massage therapy** reduce anxiety and depression in patients getting bone marrow transplants?

*Melodie Olson, Medical University of South Carolina:

Can the technique of **therapeutic touch** prevent stess-induced immune suppression in nursing and medical students about to take board exams?

*Neil A. Sonenklar, Virginia Commonwealth University:

Can **acupuncture** treatments help in the treatment of children with attention deficit hyperactivity disorder?

*Sharon W. Goodill, Hahnemann University, Philadelphia:

Can **dance and movement therapy** improve mood, body image and compliance with prescribed exercise regimens in adults with cystic fibrosis?

*Steven L. Fahrion, Menninger Clinic, Topeka, Kansas:

Can **"energetic therapy"** improve quality of life and accelerate tumor shrinkage in patients getting conventional treatment for basal cell carcinoma?

*Michael Goldstein, University of California at Los Angeles:

For what conditions might **homeopathy** be useful, and does the technique work better for clients who believe in it or who have a certain personality type?

*Patricia Francesca Newton, Good Samaritan Hospital and Medical Center, Portland, Oregon:

Can **hypnotic guided imagery** enhance mood and immune function in breast cancer patients?

*David B. Simon, Sharp Healthcare, San Diego

Can **Ayurvedic medicine** techniques, including meditation, special diet and exercises such as sun salutations and hatha yoga improve general health and prevent illness?

*Bala V. Manyam, Southern Illinois University School of Medicine:

Can an **Ayurvedic herbal remedy** derived from beans help in the treatment of Parkinson's disease? (Experiments in rats with Parkinson's symptoms)

*Lawrence H. Kushi, University of Minnesota:

Can a **macrobiotic diet** help in the treatment of cancer?

*Timothy Carl Hain, Northwestern University:

Can **T'ai Chi** movement exercises improve balance in people with mild balance disorders?

*Paul J. Eslinger, Pennsylvania State University College of Medicine:

Can **music therapy** improve social adjustment, self-perception, and general mood in people with brain injuries?

*Frank A. Scafidi, University of Miami:

Can daily 15-minute **massages** improve growth, cognitive development and immune function in preterm newborns born to HIV-infected mothers?

*Howard Shaffer, North Charles International Health Research and Training Foundation, Cambridge, Massachusetts:

Can weekly **yoga** sessions reduce alcohol and drug use, criminal activity and drop-out rates among addicts enrolled in a methadone maintenance treatment program?

*Wen-hsien Wu, University of Medicine and Dentistry of New Jersey:

Can **Qi Gong**, an ancient form of Chinese medicine, help in the treatment of reflex sympathetic dystrophy, a chronic disease of the nervous system?

*Douglas E. DeGood, University of Virginia:

Can **massage therapy** reduce anxiety, pain and the need for follow-up care in women who have undergone surgery for uterine cancer?

Source: Wash. Post, Nov. 9, 1993 (Health News), at 7-8

Appendix B

MEDICAL PRACTICE ACT LEGISLATION ACCOMMODATING THE PRACTICE OF COMPLEMENTARY HEALTH CARE BY PHYSICIANS

(Operative language in italicized text)

Enacted Legislation

ALASKA

[Alaska Stat. § 08.64.326(a)(8)(A)]

08.64.326.

(a) The board may impose a sanction if the board finds after a hearing that a licensee

. . .

(8) has demonstrated

(A) professional incompetence, gross negligence, or repeated negligent conduct; *the board may not base a finding of professional incompetence solely on the basis that a licensee's practice is unconventional or experimental in the absence of demonstrable physical harm to a patient*;

. . .

WASHINGTON

[Wash. Rev. Code Ann. § 18.130.180(4)]

18.130.180.

The following conduct, acts, or conditions constitute unprofessional conduct for any license holder or applicant under the jurisdiction of this chapter:

. . .

(4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. *The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed*;

. . .

NORTH CAROLINA

[N.C. Gen. Stat. § 90-14(a)(6)]

90-14.

(a) The Board shall have the power to deny, annul, suspend, or revoke a license, or other authority to practice medicine in this State, issued by the Board to any person who has been found by the Board to have committed any of the following acts or conduct, or for any of the following reasons:

. . .

(6) Unprofessional conduct, including, but not limited to, departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice, or the ethics of the medical profession, irrespective of whether or not a patient is injured thereby, or the committing of any act contrary to honesty, justice, or good morals, whether the same is committed in the course of his practice or otherwise, and whether committed within or without North Carolina. *The Board shall not revoke the license of or deny a license to a person solely because of that person's practice of a therapy that is experimental, nontraditional, or that departs from acceptable and prevailing medical practices unless, by competent evidence, the Board can establish that the treatment has a safety risk greater than the prevailing treatment or that the treatment is generally not effective.*

. . .

Unenacted Legislation

NEW YORK

[**1993-1994 Regular Session** (Assembly Bill 5411-B, proposing an amendment to N.Y. Educ. Law §§ 6527 and 6532)]

6527.

. . .

(6) A physician may administer alternative medical treatments as defined in paragraph b of this subdivision to a patient provided that the rights of the patient are protected by the following:

a. The physician has obtained a written, informed consent of the patient, having disclosed to the patient that the general nature of the practice, or the particular treatment, or the pattern of treatment is alternative. The physician must also disclose such conventional options or alternatives thereto and the reasonable foreseeable risks and benefits involved as a reasonable medical practitioner would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation.

b. For the purposes of this section an alternative medical treatment is defined as: (i) a treatment not recognized by a speciality board member of the American board of medical specialties, but is (ii) a treatment using therapeutic agents listed in the United States pharmacopoeia, United States homeopathic pharmacopoeia, or the national formulary, or (iii) a treatment which has been demonstrated in a substantial body of the medical literature, or through professional conferences sponsored by medical societies, hospitals, accredited medical colleges or academies, not-for-profit associations incorporated for the advancement of medical science, or federal health institutes, to exert a favorable influence in similar conditions, or (iv) a treatment undertaken in participation with an experimental study approved by the national institutes of health, or by an institutional review board under the authority of the federal food and drug administration and conducted pursuant to generally accepted protocols, including outcome based studies, for medical research.

6532.

. . .

2. Nothing in this article shall be interpreted to allow a finding of professional misconduct on the sole basis that a licensee's practice includes alternative medical treatments, however, the inclusion of alternative medical treatments does not preclude any other finding of professional misconduct based upon the definitions of professional misconduct listed in section sixty-five hundred thirty of this article.

FLORIDA

[**1993 Regular Session** (House Bill 1183/Senate Bill 622, proposing an amendment to Fla. Stat. §455.227)]

455.227.

. . .

(5) The Board may not take action against the lisense of nor discipline a licensee for the use of nontraditional treatment if it does not injure the patient or create an unreasonable risk that the patient will be harmed.

MARYLAND

1. **1993 Session** (House Bill 383, proposing an amendment to § 14-404 of the Health Occupations Article)

14-404.

(a) Subject to the provisions of subsection (c) of this section and the hearing provisions of § 14-405 of this subtitle, the Board, on the affirmative vote of a majority of its full authorized membership, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee [commits specified acts]:

. . .

(c) The Board may not reprimand any licensee, place any licensee on probation, or suspend or revoke a license solely because the licensee uses a complementary medical method, if the licensee:

(1) complies with recognized standards of medical practice; and

(2) documents the patient's informed consent for the use of the complementary medical method in the patient's medical record.

2. **1992 Session** (House Bill 526, proposing an amendment to § 14-404 of the Health Occupations Article)

14-404.

(a) Subject to the provisions of subsection (c) of this section and the hearing provisions of § 14-405 of this subtitle, the Board, on the affirmative vote of a majority of its full authorized membership, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee [commits specified acts]:

. . .

(c) The Board may not reprimand any licensee, place any licensee on probation, or suspend or revoke a license solely because the licensee uses nontraditional medical methods if the licensee:

(1) complies with recognized standards of medical practice; and

(2) documents the patient's informed consent for use of the nontraditional medical method in the patient's medical record.

3. **1991 Session** (House Bill 678, proposing an amendment to §§ 14-205 and 14-404 of the Health Occupations Article)

14-205.

. . .

(b) (1) In addition to the duties set forth elsewhere in this title, the Board shall:

. . .

(iv) develop a model informed consent form for use by the licensee's [sic] whose practice is in whole or in part unconventional or experimental.

. . .

14-404.

(a) Subject to the provisions of subsection (c) of this section and the hearing provisions of § 14-405 of this subtitle, the Board, on the affirmative vote of a majority of its full authorized membership, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee [commits specified acts]:

. . .

(c) In the absence of demonstrable physical harm to a patient, the Board may not reprimand any licensee, place any licensee on probation, or suspend or revoke a license solely because the licensee's practice is unconventional or experimental.

STATE LAWS ACCOMMODATING THE USE OF ALTERNATIVE HEALTH CARE THERAPIES BY PHYSICIANS

A Reference Document Containing the Texts of Recently Enacted Laws

December 1995

David M. Sale, J.D., LL.M.

STATE LAWS ACCOMMODATING THE USE OF ALTERNATIVE HEALTH CARE THERAPIES BY PHYSICIANS

(Operative Language in Italicized Text)

ALASKA

Ch. 126, § 22, Acts of 1990

(a) The [state medical] board may impose a sanction if the board finds after a hearing that a licensee

. . .

(8) has demonstrated

(A) professional incompetence, gross negligence, or repeated negligent conduct; *the board may not base a finding of professional incompetence solely on the basis that a licensee's practice is unconventional or experimental in the absence of demonstrable physical harm to a patient*; [Alaska Stat. § 08.64.326(a)(8)(A)]

WASHINGTON*

Ch. 332 , § 34, Acts of 1991

The following conduct, acts, or conditions constitute unprofessional conduct for any license holder or applicant under the jurisdiction of this chapter:

. . .

(4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. *The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed*; [Wash. Rev. Code Ann. § 18.130.180(4)]

*The Washington statute forms part of the state's Uniform Disciplinary Act which regulates various health occupations in addition to physicians.

NORTH CAROLINA

Ch. 241, Acts of 1993

(a) The Board [of Medical Examiners] shall have the power to deny, annul, suspend, or revoke a license, or other authority to practice medicine in this State, issued by the Board to any person who has been found by the Board to have committed any of the following acts or conduct, or for any of the following reasons:

. . .

(6) Unprofessional conduct, including, but not limited to, departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice, or the ethics of the medical profession, irrespective of whether or not a patient is injured thereby, or the committing of any act contrary to honesty, justice, or good morals, whether the same is committed in the course of his practice or otherwise, and whether committed within or without North Carolina. *The Board shall not revoke the license of or deny a license to a person solely because of that person's practice of a therapy that is experimental, nontraditional, or that departs from acceptable and prevailing medical practices unless, by competent evidence, the Board can establish that the treatment has a safety risk greater than the prevailing treatment or that the treatment is generally not effective.* [N.C. Gen. Stat. § 90-14(a)(6)]

SOUTH DAKOTA

Ch. 272, Acts of 1993

The South Dakota state board of medical and osteopathic examiners may cancel, revoke, suspend or limit the license of any physician, surgeon or osteopathic physician or surgeon issued under this chapter upon satisfactory proof in compliance with chapter 1-26 of such a licensee's gross incompetence, or unprofessional or dishonorable conduct or proof of a violation of this chapter in any respect. *However, the board may not base a finding of unprofessional or dishonorable conduct solely on the basis that a licensee practices chelation therapy.* [S. D. Codified Laws Ann. § 36-4-29]

OKLAHOMA

Ch. 323, Acts of 1994

Sections 481 through 518 of Title 59 of the Oklahoma Statutes shall be known and may be cited as the "Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act". It is the intent that this act shall apply only to allopathic and surgical practices and to exclude any other healing practices. Allopathy is a method of treatment practiced by recipients of the degree of Doctor of Medicine, but specifically excluding homeopathy. The terms medicine, physician and drug(s) used herein are limited to allopathic practice. [Okla. Stat. tit. 59, § 480].

Nothing in the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act shall prohibit services rendered by any person practicing any nonallopathic healing practice. [Okla. Stat. tit. 59, § 492(F)].

The [State] Board [of Medical Licensure and Supervision] shall not deny a license to a person otherwise qualified to practice allopathic medicine within the meaning of this act solely because the person's practice or a therapy is experimental or nontraditional. [Okla. Stat. tit. 59, § 493.1(M)].

The Board may take disciplinary action for unprofessional or unethical conduct as deemed appropriate base upon the merits of each case and as set out by rule. *The Board shall not revoke the license of a person otherwise qualified to practice allopathic medicine within the meaning of this act solely because the person's practice or a therapy is experimental or nontraditional.* [Okla. Stat. tit. 59, § 509.1(D)(2)].

NEW YORK

Ch. 558, Acts of 1994

This article [concerning the medical profession] shall not be construed to affect or prevent the following:

. . .

e. *The physician's use of whatever medical care, conventional or non-conventional, which effectively treats human disease, pain, injury, deformity or physical condition.* [N.Y. Educ. Law § 6527(4)(e)].

A state board for professional medical conduct is hereby created in the department [of health] in matters of professional misconduct. . .The board for professional medical conduct shall

consist of not fewer than eighteen physicians licensed in the state for at least five years, two of whom shall be doctors of osteopathy, *not fewer than two of whom shall be physicians who dedicate a significant portion of their practice to the use of non-conventional medical treatments who may be nominated by New York state medical associations dedicated to the advancement of such treatments*, and not fewer than seven lay members. [N.Y. Public Health Law § 230(1)]

If the investigation of cases referred to an investigation committee involves issues of clinical practice, medical experts shall be consulted. Experts may be made available by the state medical society of the state of New York, by county medical societies and specialty societies, *and by New York state medical associations dedicated to the advancement of non-conventional medical treatments.* . . . [N.Y. Public Health Law § 230(10)(a)(ii)]

A physician discipline process evaluation panel is hereby created in the department of health to assess the physician discipline system. . .*The panel shall also report to the governor and the legislature by June 1, 1995 concerning (i) the use of experts, including experts in medical specialties or experts in non-conventional medicine by the office of professional medical conduct in the investigation of complaints which involve issues of clinical practice, and (ii) the appointment of physicians, including physicians in a medical specialty and physicians practicing non-conventional medicine, to committees on professional medical conduct hearing a case in which a physician in such specialty or a physician practicing non-conventional medicine is the respondent.* [Ch. 735, § 6(a), Acts of 1992]

OREGON

Ch. 2, Acts of 1995 (Special Session)

The Board of Medical Examiners for the State of Oregon may refuse to grant, or may suspend or revoke a license to practice issued under this chapter for any of the following reasons:

(1)(a) Unprofessional or dishonorable conduct.

(b) For purposes of this subsection, the use of an alternative medical treatment shall not by itself constitute unprofessional conduct. For purposes of this paragraph:

(A) "Alternative medical treatment" means:

(i) A treatment that the treating physician, based on the physician's professional experience, has an objective basis to believe has a reasonable probability for

effectiveness in its intended use even if the treatment is outside recognized scientific guidelines, is unproven, is no longer used as a generally recognized or standard treatment or lacks the approval of the United States Food and Drug Administration;

(ii) A treatment that is supported for specific usages or outcomes by at least one other physician licensed by the Board of Medical Examiners; and

(iii) A treatment that poses no greater risk to a patient than the generally recognized or standard treatment.

(B) "Alternative medical treatment" does not include use by a physician of controlled substances in the treatment of a person for chemical dependency resulting from the use of controlled substances. [Ore. Rev. Stat. § 677.190(1)]

Appendix D

Synopsis of Complementary Medical Modalities

Therapeutic Massage

One form of Bodywork to improve the structure and functioning og the human body by reducing pain, soothing injured muscles, stimulating circulation (blood and lymphatic), and promoting deep relaxation by tension release. Conditions that can be helped include muscle spasm and pain, lordosis and scoliosis, headaches, whiplash injury, TMJ, asthma, emphysema, adjunct in treating cardiovascular, neurological and gynecological problems, improved body motion and facilitate the elimination of toxins from the body.

Acupuncture

Health is determined by a balanced fow of chi (qi), the vital life energy present in all organisms. Chi (qi) circulates in the body along 12 major energy pathways, called meridians, each linked to specific organ systems. Over 300 acupoints are within the meridian system that can be stimulated to enhance the flow of chi. Special needles incerted into acupoints help correct and rebalance the flow of energy - relieving pain and restoring health. Numerous conditions helped include the common cold, addictions, chronic fatigue syndrome, pain relief, migraines, allergies, depression, menstrual problems, surgical anesthesia, and AIDSimmune function.

Homeopathy

Derived from Greek meaning, "similar and suffering." Homeopathic remedies are dilutions of natural substances from plants, mineral and animals. Based on the principle "like cures like,' these remedies match different symptom "profiles" of illness, and stimulate the body's natural healing response. Other principles are " the more a remedy; is diluted, the greater its potency" and " an illness is specific to an individual." The same substance that in large doses produces symptons of an illness, in very minute doses cures it. ("The Law of Similars") Certain vaccines and allergy desensitization are based on the the "Law of Similars." Homeopathy is a complete system of natural medicine that can have a therapeutic effectt on almost any disease or health condition. This includes diabetes, arthritis, asthma, epilepsy, skin disorders,allergies, emotional disorders, colds, headaches, fatigue, PMS, pain, gastrointestinal disorders, and injuries.

Herbal Medicine

The most ancient form of health care utilizing dried plants as medicine. Approximately 25% of prescription drugs are derived from trees, shrubs or herbs. Herbs are used for PMS, gastrointestinal disturbances, insomnia, heart disease, cancer, HIV, colds, skin rashes, stress, hypertension, allergies, and arthritis. Herbs contain naturally occuring chemicals with biologic activity.

Chiropractic

Through adjustments of the spinal column and joints, the body's nervous system and natural defense mechanisms can be influenced to alleviate pain and improve general health. The CNS coordinates and controls the functions of the other systems of the body. Uses include treating back problems, headaches, injuries and trauma, respiratory conditions, gastrointestinal, central nervous system disorders, hypertension, cardiac problems, sinusitis, and emotional disorders. Chiropractic recognizes the inherent ability to heal itself from physical injury or mental and environmental stress. Nerve interference caused by misalignments in the spine (subluxations) and the body's defenses can be diminished.

Ayurvedic

Means "science of life" with equal emphasis on mind, body and spirit to restore the innate harmony of the individual. The keystone is "constitution" - overall health profile of the individual, including strengths and susceptibilities. The metabolic body type is identified with the goal being harmony with the environment including dietary changes, exercise, yoga, meditation, massage, herbal tonics, herbal sweat baths, medicated enemas, sun and breathing. Metabolic body types (doshas) - 3 types vata, pitta, and kapha.

Biofeedback Training

Method of learning how to consciously regulate normally unconscious bodily functions (ex. Breathing, heart rate, blood pressure) to improve overall health through the use of electronic devices including monitoring skin temperature, galvanic skin response, EMG, EKG, and EEG. Therapeutic examples - stress reduction, headaches, asthma, reconditioning injured muscles and relieve pain, hypertension, insomnia, GI disorders, and TMJ.

Nutritional Therapy

The use of vitamin and mineral supplementation is used to maintain optimal physical and psychological health, and promote longevity and chronic disease prevention. Diet alone may not be sufficient to supply the nutrient necessary of overall good health. Antioxidants (Vitamins C, A, E and selenium) are effective in decreasing free radical formation. Conditions helped by correcting nutritional deficiencies are too many to mention.

Neurolinguistic Programming / Visualization

NLP helps detect and reprogram unconscious patterns of language, thought and behavior to alter psychological responses and enhance the healing process. NLP focuses on how people learn, communicate, change, grow and heal. "Neuro" refers to the way the brain works with consistent and detectable patterns. "Linguistic" refers to verbal and nonverbal expressions of the brain's thinking patterns. Autonomic body changes and breathing such as skin color changes, moisture changes in the lips or eyes are utilized. Is used in treating patients with AIDS, cancer, allergies, arthritis, Parkinson Syndrome, and migraine headache.

Environmental Medicine

Food and environmental allergens (pollens, dust, molds, chemicals) may cause allergic reactions that influence many diseases including asthma, hay fever, headaches, depression, fatigue, arthritis, gastrointestinal disorders, recurrent ear infections, hyperactivity and PMS. Chemicals include insecticides, herbicides, plastics, formaldehyde, petrochemicals, and lfood additives. Genetics, poor nutrition, infections, chemical exposures, physical or emotional stree, frequent use of antibiotics or steroids, thyroid and adrenal disorders, physical trauma, electromagnetic disturbances, and dental amalgams can be underlying contributing factors.

Chelation Therapy

Used appropriately, a safe and effective method for removing toxic metals from the bloodstream. Chelating agents administered intravenously increase blood flow and decrease calcium arterial plaque. Chelation therapy may reverse atherosclerosis, prevent heart attacks and strokes, and as used by some as an alternative to bypass surgery and angioplasty. EDTA is presently FDA approved only for lead and heavy metal toxity.

Colonic Therapy

The colon is a major organ for eliminationg body waste whose function is essential for good digestion and the proper absorption of nutrients. Health can be compromised if waste products and toxins are not eliminated in a regular manner. Colon therapy uses a series of colonic water flushes to clean and detoxify the lower intestinal and aid in the reconstitution of the intestinal flora. Conditions treated by colon therapy include back pain, headache, gastrointestinal problems, sinus congestion, skin problems, decreased concentration and fatigue.

Meditation

Any activity that keeps the attention pleasantly anchored in the present moment - neither reverting to past memories or preoccupied with future plans. The goal is to balance a person's physical, emotional, and mental states. Technique #1 "Concentrative meditation" focuses attention on the breath, an image, or a sound (mantra) to still the mind and allow greater clarity and awareness to emerge. Technique #2 "Mindfulness Meditation" involves opening the attention to awareness of sensations, feelings, images, thoughts, sounds and smells. Treatment for stress and pain management, hypertension, heart disease, AIDS, autoimmune disorders, and addictions.

Yoga

Means "union" - the integration of physical, mental and spiritual energies to enhance health and well-being (mind-body unity). Classical Yoga is organized into eight "limbs" - the first four for posture and breathing practices and the second four with stages of meditation. Yoga postures include meditative and therapeutic types. Pranayama focuses on breath regulation. The connection of breath and mind is a basic principle of yoga. Yoga is used for stress reduction, hypertension, heart rate regulation, asthma, gastrointestinal disorders, pain reduction, addictions, improved memory, menstrual disorders, thyroid disorders, and allergies.

Addendum

The therapeutic benefits of the complementary medical methods are based on information from the text " Alternative Medicine" by Burton Goldberg and reflect the impressions of the practicioners of these modalities.

Apppendix E

I. **Osteoarthritis** -- We compared NSAIDS (aspirin family compounds) and glucosamine (a cartilage compound used in complementary medicine) for this problem. Glucosamine has been studied both in placebo-controlled studies as well as in head-on studies against Motrin, a commonly used allopathic NSAID medication for osteoarthritis. These studies show that for the first few weeks of treatment Motrin is more effective, but after this time the Glucosamine becomes more effective and was shown to be more effective than Motrin at the end of the six-week period. The Glucosamine was not shown to have any side effects. Motrin was found to have the side effects of potentially fatal stomach bleeding and other bleeding disorders, kidney and liver toxicity, and other less common reactions. The cost of Glucosamine is taken from a major company catalogue. The cost for Motrin and other nonsteroidals commonly used for osteoarthritis is taken from the Medical Letter (a respected newsletter on drug therapies). The data and experience in the medical community suggests that both alternative and complementary methods for treatment of osteoarthritis are very effective and can be used together to achieve even greater levels of efficacy. Figure 1 also shows comparative costs and risks for treatment of this disease.

II. **Disc Disease** -- We chose intravenous colchicine as the complementary method for treating this disease and surgery (laminectomy) as the conventional treatment for this disease. We have chosen to define this disease as being persistent or refractory to conservative management for over six weeks. An open and controlled study done on patients with this disease using colchicine shows the colchicine therapy to be a very effective modality. Surgery is often very effective in many patients as well. There are no head-on studies comparing both of these modalities in the same trial and, therefore, we simply noted the costs and risks of each of these procedures. Experience suggests that these two procedures are not mutually exclusive and that the colchicine therapy appears to be very effective in the initial conservative management of disk disease with surgery being done if this modality fails. Colchicine also seems to have a place for treating patients who have failed surgery.

III. **Severe Congestive Heart Failure** -- Again, there are no head-on studies comparing traditional and complementary methods for this illness. We have chosen Coenzyme Q-10 as a treatment that has been found by complementary physicians and by the scientific literature to be very effective in treating congestive heart failure (even very severe cases). We compared these to "ACE inhibitors", a family of medications often used in severe congestive heart failure in traditional medicine and surgery (e.g. heart transplant). Again, no head-on studies comparing these are available and Figure 1 simply compares the costs and side effects of these approaches.

These approaches are complimentary and work well together. The patient seems to be benefited most by combining the two approaches.

IV. **Elevated Cholesterol** -- We are comparing garlic which has been found to be effective in lowering cholesterol to the HMG Co-A reductase (Mevacor) family of medications which are commonly used in treating high cholesterol by traditional physicians. We have excluded Lopid and Questran from comparison. Studies have shown that these medications (despite their continued use) do not prolong life. The Mevacor family has been found to prolong life as has niacin (another method used by both complementary and traditional physicians). Again, no head-on comparisons of the traditional versus complementary methods have been done and therefore the relative costs, risks, and efficacies of both of these are simply noted in Figure 1. Once again, experience suggests that the optimum way to treat the patient is to combine these modalities as they are not mutually exclusive but are often complementary.

V. **Benign Prostatic Hypertrophy** -- The complementary treatment for this includes herbal remedies such as serenoa repens. The traditional treatment for BPH is surgery. Proscar is used to slow progression of BPH, but has not been shown to reverse the symptoms. Several other complementary methodologies have been found to improve symptoms. Because of this we will compare the herbal remedies to both Proscar and TURP surgery. Once again, clinical experience suggests that the optimum approach for these patients is to use the herbal remedies initially followed by surgery if the patient fails treatment with the herbals or Proscar.

VI. **Carpal Tunnel Syndrome** -- The complementary method we have chosen is to use Vitamin B6 plus wrist splints. The traditional method is surgical release of the nerve. Figure 1 again compares the costs and risks. Once again, clinical experience suggests that the optimum treatment for patients is to use the B6 and wrist splints first, followed by surgery in the small percentage of patients (usually those having problems caused by repeated and persistent traumatic injury such as hammering or typing) who continue to be symptomatic.

Commission on Complementary Medical Methods
Meeting with Complementary Care Physicians - 6/14/94

On June 14, 1994, a meeting was held at the Columbia School of Traditional Acupuncture to discuss complementary medicine. Attending this meeting were four complementary medical practitioners - Jacob Teitelbaum, M.D., Alan Gaby, M.D., Peter Hinderberger, M.D., and Benyamin Rothstein, D.O., as well as three members of the commission - Gail Geller, Caril Price and Richard Layton.

Some of the treatments discussed at this meeting included the use of Colchicine vs. medication for disc disease. Cost comparison: It was mentioned that the cost of Colchicine is five to ten cents per pill compared to Naprosyn which costs $1.00 to $1.50 per pill. Treating Serous Otitis Media with homeopathy, clinical hypothyroidism, IV vitamin drips (Meyers Cocktail) and various treatments for congestive heart failure including: CoQ10 and Taurine was mentioned. In Italy CoQ10 is used extensively for congestive heart failure.

Questions were asked of the commission members about the purpose of commission. We explained our problem with no budgetary money for this project and that qualitative research was necessary - necessitating the meeting to gather information with complementary care physicians. It was also mentioned to the complementary care physicians that this commission was evaluating the cost, benefits and risks of various complementary medical approaches used by doctors and the necessity of informing the public of what was available.

Most important in regard to what direction the state of Maryland should be taken in regard to complementary care, the physicians available had the following comments:

1) Patients' should have the right to choice of care.
2) There should be no restrictions to access to complementary care.
3) With peer review, quality assurance should consist of at least one participant familiar with complementary care medicine when complementary medicine is an

issue.

4) Consent forms - inform patient of conventional or complementary care with a consent form elaborating traditional and non-traditional methods.
5) Establishing specific boards with board certification should be considered.
6) The commission should focus on five to six treatments and compare to more conventional approaches.
7) The importance of the commission staying on target and the need to focus.
8) The goal of complementary and conventional medicine should be the best outcome for patients.

Of considerable importance was the unanimous feeling that the legislative report by David Sale was a definite step in the right direction. The various legislative proposals in the Sale report should be evaluated by the Complementary Care Commission for consideration by the state legislature. By evaluating the various legislative options, the complementary care physicians felt that this would best assure those factors previously mentioned, especially good access to complementary care and the patient's right of choice, would be addressed by the Commission.

MEETING WITH CONVENTIONAL PHYSICIANS

Overview - A meeting was held on September 27, 1994 with three conventional medical practitioners - (1) Boris Kerzner, M.D., Internist; (2) Ronald Cohen, M.D., Neurosurgeon; and (3) Tim Krohe, M.D., Internist; and four members of the Commission - Caril Price, Gail Geller, Sidney Seidman, and Richard Layton.

Each participant was given a summary of what the Complementary Care Commission has discussed up to the present time. This included a summary of House Bill 382, the approved definition of complementary medicine, the letter sent to physicians and osteopaths published in BPQA, the data collection draft reviewed at the last meeting, the David M. Sale report, and the meeting with the four complementary care practitioners on June 10, 1994.

Several examples of negative and positive experiences were mentioned. Negative experiences included:

1. A patient who received two weeks of massage and chiropractic care for scoliosis. This patient was seen in the emergency room with a blood pressure change and the diagnosis of an aneurysm.
2. A young female committed suicide who had been diagnosed by a complementary care practitioner with Systemic Candidiasis and was told she had an incurable medical illness and had not sought out psychotherapy.
3. A patient with an incurable malignancy who is paying $500.00 per week for alternative medical care.

The positive experiences were:

1. Acupuncture being effective for surgical anesthesia.
2. Vitamin therapy to treat premenstrual syndrome.

Problems that were pointed out at this meeting included the following:

1. The standards of regulation of peer review - consider complementary care review as an adjunct to BPQA.
2. When does a patient stop conventional treatment and look at alternative?
3. Our definition of complementary care is a problem (too non-specific).
4. Complementary medicine is not as formalized with a lack of organization to show validity or non-validity.
5. Need to recognize a charlatan.
6. Identify risks.
7. Economic factors.
8. Identify life-threatening conditions.

Random comments made at the meeting included:

1. There is more risk and dangers with conventional medical therapy.
2. Surveys are more likely to be successful if CME credits are offered. With money as the incentive, survey would go to the trash can.
3. Patient assured of minimal requirements with conventional medicine.
4. Complementary medicine is subjected to a higher standard than conventional medicine.
5. Anecdotes and single cases are not reliable.
6. Scientific method is a western concept versus acupuncture being available for several thousand years.
7. Chiropractors and Acupuncturists can help more back problems than a Neurosurgeon.
8. The choice of treatment requires standards that are outside the scope of this Commission.
9. There is a need to publish anecdotes.
10. Balance of risk and benefits.

Goals should include:

1. To combine conventional and complementary medicine.
2. Level the playing field.
3. What is acceptable and not acceptable.
4. Visible standards of care.
5. Cannot endanger the patient.
6. Free interchange of knowledge.

State of Maryland

Governor's Commission on Complementary Medical Methods

William Donald Schaefer
Governor

Caril E. Price, Ed.D.
Chairperson

Dear Maryland Physician:

As Chairperson of the Governor's Commission on Complementary Medical Methods I am writing to request your assistance with the enclosed questionnaire. Your name was selected at **random** from a pool of physicians who currently practice in Maryland.

The Commission has developed this questionnaire in order to collect the appropriate data to complete the legislative charges as mandated in 1993, by the Governor and General Assembly in House Bill 382. Specifically, the legislative charges are as follows:

- Defining which health care methods are complementary medical methods being used by physicians in Maryland.
- Evaluating the costs, benefits, and risks associated with the use of complementary medical methods.
- Determining how best to inform patients of the benefits and risks associated with the use of complementary medical methods and the availability of other methods of treatment.

This questionnaire has been design to allow the physician to complete the responses in an organized and efficient manner. Your signature will not be required, however, if you prefer to sign your name then do so. Kindly return the questionnaire by Friday, February 3, 1995 in the enclosed self-addressed stamped envelope.

The Commission appreciates your time given to complete this task and your interest/concerns in the practice of complementary medical methods. As a Maryland Physician, we thank you for joining us in our mission to protect and provide the highest quality of health care to the citizens of Maryland.

Sincerely,

Caril E. Price

Caril E. Price, Ed.D.
Chairperson

TDD for The Deaf:
Baltimore Area 383-7555
D.C. Metro Area 565-0451

1. In what year did you graduate from medical school? . . . . . 19__

2. Did you graduate from a U.S. medical school? . . . . . Yes (1) No (2)

3. When you were in medical school, did you learn about complementary/alternative medicine? (Circle one response)

   No, there weren't any lectures/courses in it 1

   No, there was a lecture/course but it wasn't a priority for me 2

   Yes, there was a required lecture/course 3

   Yes, I chose the lecture/course as an elective 4

4. Have you received additional/specialized training in one or more forms of complementary medicine (e.g., homeopathy, acupuncture, ayurveda, etc.)?

   Yes (1) No (2)

   If yes, please describe _____

5. How often do you discuss with patient the extent to which they seek complementary medical care?

   With all my patients 1

   With most of my patients 2

   With half of my patients 3

   With less than half of my patients 4

   Never 5

6. Assume that a complementary technique is available to treat each of the following conditions. Do you think it is appropriate for patients who suffer from these conditions to try this technique? (Circle the one number (1-3) to the right of each condition that corresponds to your answer.)

	Yes	No	Undecided
Asthma/Allergies	1	2	3
Migraines	1	2	3
Chronic Fatigue Syndrome	1	2	3
Low Back Pain	1	2	3
Cancer	1	2	3
Chemical Dependency	1	2	3
Attention Deficit/Hyperactivity Disorder	1	2	3
Chronic Otitis Media	1	2	3
Irritable Bowel Syndrome	1	2	3

7. Have you ever recommended complementary medicine to any of your patients?

Yes, I provide it (the service) myself 1

Yes, I refer my patients to specific complementary practitioners 2

Yes, I suggest they pursue it but don't make specific referrals 3

No 4

8. Of all the patients you see, approximately what proportion have you provided/recommended/referred for complementary medicine? (Circle one number)

All/nearly all 1

Half or more than half 2

Less than half (number patients per week _____) 3

Very Few 4

None 5

THE FOLLOWING QUESTION HAS FOUR PARTS (A, B, C & D). PLEASE READ THE INSTRUCTIONS CAREFULLY.

9. Indicate (A) which of the following complementary techniques you have provided yourself, (B) which of the following techniques you have made referrals for, (C) what you believe the approximate cost per service is, and (D) who you believe pays for the service.

	(A) Provided		(B) Referred		(C) Cost	(D) Who Paid		
	Yes	No	Yes	No		Patient	*Ins.	**DK
Therapeutic Massage	1	2	1	2	_____	1	2	3
Acupuncture	1	2	1	2	_____	1	2	3
Homeopathy	1	2	1	2	_____	1	2	3
Herbal Medicine	1	2	1	2	_____	1	2	3
Ayurveda	1	2	1	1	_____	1	2	3
Chiropractic	1	2	1	2	_____	1	2	3
Biofeedback	1	2	1	2	_____	1	2	3
Meditation/Yoga	1	2	1	2	_____	1	2	3
Nutritional Therapy	1	2	1	2	_____	1	2	3
Environmental Medicine	1	2	1	2	_____	1	2	3
Neurolinguistic Programming/ Visualization	1	2	1	2	_____	1	2	3
Chelation Therapy	1	2	1	2	_____	1	2	3
Colonic Therapy	1	2	1	2	_____	1	2	3
Other	1	2	1	2	_____	1	2	3

* Ins. = Insurance
**DK = Don't Know

10. Indicate which of these techniques is available in your geographic area?

	Yes	No	Unsure
Therapeutic Massage	1	2	3
Acupuncture	1	2	3
Homeopathy	1	2	3
Herbal Medicine	1	2	3
Ayurveda	1	2	3
Chiropractic	1	2	3
Biofeedback	1	2	3
Meditation/Yoga	1	2	3
Nutritional Therapy	1	2	3
Environmental Medicine	1	2	3
Neurolinguistic Programming/Visualization	1	2	3
Chelation Therapy	1	2	3
Colonic Therapy	1	2	3
Other (Specify _____	1	2	3

THE FOLLOWING THREE QUESTIONS MAY OR MAY NOT APPLY TO YOU. IF THEY DO NOT, SKIP THEM. PLEASE PRINT

11. Please describe one "successful" experience with complementary medicine (i.e., a patient that you treated, referred, observed that the treatment goal was achieved).

12. Please describe one experience with complementary medicine where there were unintended negative consequences (i.e., a patient that you treated, referred, or observed that there was either an adverse reaction or a delay in appropriate conventional treatment).

13. Please describe one experience with complementary medicine where there were unintended positive consequences (i.e., a patient that you treated, referred, or observed for whom the symptom of interest was not relieved but another complaint was addressed).

14. Have you or anyone in your immediate family ever used complementary medicine?

Yes	No	Unsure
1	2	3

15. Do you hold an academic appointment?

Yes	No

16. In what type of geographic area is your principal practice? (Circle one number.)

Metropolitan/central city 1

Metropolitan/suburban 2

Small city/town 3

Rural 2

17. What are your most frequent sources of information about new medical problems and practices? (Circle under "yes" if you use the source regularly, under "no" if you do not.)

	Yes	No
Discussion with other practitioners	1	2
Medical journals	1	2
Attendance at professional meetings	1	2
Participation in continuing education courses	1	2
Pharmaceutical reps. or literature	1	2
Other (please specify _____)	1	2

18. What is your specialty:

Internal Medicine (Indicate if subspecialty) 1

Family Practice 2

Obstetrics/Gynecology 3

Pediatrics (Indicate if subspecialty_____) 4

Surgery (Indicate if subspecialty_____) 5

Psychiatry 6

Other (Specify_____) 7

19. What is your gender:

Male 1

Female 2

20. What is your race/ethnic group:

White, non-Hispanic 1

African-American 2

20. (Continued)

Hispanic 3

Asian/Pacific Islander 4

Native American 5

Other 6

Thank you for your time. Please fold the questionnaire and return it in the stamped envelope we provided.

_____ _____

Name (Optional) Date

Appendix H

Outcome Variables:

1) Percent of patients with whom physicians discuss complementary medicine;
2) Attitudes toward the appropriateness of using complementary techniques for various conditions;
3) Frequency of referral for complementary medicine;
4) Types of modalities to which referrals are made; and
5) Knowledge of availability of various complementary techniques in their geographic area.

Predictor Variables:

1) Specialty;
2) Year of Graduation: Year of graduation was trichotomized based on their frequency distribution. The three categories were those who graduated before 1965, those who graduated between 1966 and 1979, and those who graduated after 1980;
3) Gender:
4) Graduation from Foreign Medical School (yes, no);
5) Geographic Area: Respondents were grouped into those who reported practicing in a rural area vs. elsewhere (urban, suburban, small city);
6) Family Member has used Complementary Medicine (yes, no).

Analysis: Once all variables were in categorical form, cross-tabulations were used to look at the relationship between outcome and predictor variables. All analyses were done using SPSS/PC+.

Gender
13,793 (77%) are male
4,203 (23%) are female

In our sample, 81% of respondents are male and 19% of respondents are female. Therefore, there is no significant difference in response rate by gender.

Specialty
1,066 (6%) are family/general practitioners
3,583 (20%) are internists
1,041 (6%) are obstetrician-gynecologists
1,546 (9%) are pediatricians
2,554 (14%) are surgeons

1,223 (7%) are psychiatrists
7,072 (39%) are other

In our sample, 10% of respondents are family practitioners, 30% are internists, 5% are ob/gyn, 11% are pediatricians, 10% are surgeons, 8% are psychiatrists and 26% are other. Therefore, there are slight differences in response rate by specialty. Respondents to our survey appear to disproportionately represent family medicine and internal medicine, and under represent surgeons. This, however, could be an artifact of coding, since we do not know the exact ways in which the AMA categories are defined, or which categories of respondents classified their specialty as "other".

Country of Graduation — 12,999 (72%) are U.S. medical graduates
4,978 (28%) are foreign medical graduates

In our sample, 73% of respondents are U.S. medical graduates and 25% of respondents are foreign medical graduates. Therefore, there is no significant difference in response rate by country of graduation.

Age — 9,280 (52%) are $\leq$ 44 years of age
3,783 (21%) are 45-54 years of age
4,933 (27%) are $\geq$ 55 years of age

Since we used year of graduation as the important demographic characteristic in our sample, we are not able to compare the age of respondents in our sample to the statewide age distribution. However, by collapsing the two younger age groups in the statewide distribution (i.e., those who are 54 years of age or younger), we are able to devise categories that approximate the breakdown in our sample. For example, those who are 54 years of age or younger (73% of non-federal physicians in the state) are likely to have graduated after 1966. Those who are 55 years of age or older are likely to have graduated before 1966. In our sample, 74% of respondents graduated after 1966 and 26% of respondents graduated before 1966. Therefore, there is no significant difference in response rate by year of graduation. Overall, the distribution of respondents to our survey closely parallels the distribution of physicians in the state. The only minor exception appears to be among specialties. We do not have information on the ethnic distribution of physicians in the state. However, the ethnic distribution of physicians who responded to our survey is as follows: 76% are white, 17% are Asian/Pacific Islander, 3% are Hispanic, 3% are African-American and 2% are "other".

TABLE I

Question 6: Assume that a complementary technique is available to treat each of the following conditions. Do you think it is appropriate for patients who suffer from these conditions to try this technique?

Percentages in order of frequency of appropriateness

Condition	**Yes**	**No**
Low Back Pain	61.7	18.0
Migraines	56.0	25.2
Chronic Fatique Syndrome	52.5	22.1
Irritable Bowel Syndrome	47.1	28.5
Chemical Dependency	39.8	36.7
Hyperactive Disorder	32.7	41.4
Asthma/ Allergies	32.3	49.6
Cancer	20.9	59.7
Otitis Media	14.6	68.6

TABLE II

Question 9: Indicate which of the following techniques you have made referrals for.

Percentages in order of frequency of referral

Technique	Yes	No
Biofeedback	33.8	66.2
Chiropractic	30.1	69.9
Nutrition Therapy	27.2	72.8
Acupuncture	27.1	72.9
Therapeutic Massage	22.2	77.8
Meditation/ Yoga	15.8	84.2
Environmental Medicine	10.4	89.6
Homeopathy	8.7	91.3
Neurolinguistic Programing	6.9	93.1
Herbal Medicine	5.7	94.3
Ayurveda	4.4	95.6
Chelation Therapy	3.9	96.1
Colonic Therapy	3.0	97.0

TABLE III

Question 10: Indicate which of these techniques is available in your geographic area.

Percentages in order of frequency of geographic availability

Technique	Yes	No	Unsure
Chiropractic	88.4	1.1	10.4
Acupuncture	78.1	4.1	17.8
Biofeedback	69.1	3.0	27.9
Therapeutic Massage	63.0	3.4	33.6
Nutrition Therapy	62.4	1.9	35.7
Mediation/ Yoga	59.2	4.5	36.2
Homeopathy	48.3	6.9	44.8
Herbal Medicine	44.5	8.7	46.8
Environmental Medicine	30.2	6.6	63.2
Chelation Therapy	23.8	8.4	67.8
Neurolinquis. Programing	21.3	5.4	73.3
Colonic Therapy	19.0	7.0	73.6
Ayurveda	14.4	8.9	76.7

Appendix I

COMMISSION ON COMPLEMENTARY MEDICAL METHODS

Minority Report

The Commission on Complimentary Medical Methods (the "Commission") worked hard to carry out the legislative mandate to define and evaluate complimentary medical methods. However, many of the Commission members came to this task with preconceived opinions of complimentary medicine. The Commission was composed consumers of complimentary medicine, the proprietor of a health food store, and seven physician members, three of whom practiced some type of complimentary medicine, and two physician members of the Maryland Board of Physician Quality Assurance (the "BPQA"). This diverse composition led to open and frank discussions, but often served only to reaffirm pre-existing ideas.

The Commission was charged by the legislature with the following tasks:

> 1. To define which health care methods are complimentary medical methods; and
>
> 2. To study how to allow the use of complimentary medical methods by Maryland physicians with patients who wish to be treated with complimentary medical methods for their medical conditions.

HB 382, 1993. To carry out its task, the Commission solicited information from a pool of Maryland physicians representing those who utilized complimentary methods, as well as practitioners of traditional medicine. The Commission found that Maryland physicians and patients often used complimentary methods in ways similar to their use throughout the United States. Furthermore, the Commission's survey indicated that while 46% of Maryland physicians have recommended some form of complimentary medicine to patients, 8% actively incorporate such methods into their medical practices. Final Report, Commission on Complimentary Medicine.

The Commission's report includes the following recommendation:

> III. The Commission believes that if and when the care provided by a physician who practices complimentary medicine is subjected to the Board of Physician Quality Assurance (BPQA) scrutiny, the BPQA should enlist the expertise of a board certified medical doctor who practices complimentary medicine of the same or similar type. Therefore, in such cases, the COMMISSION RECOMMENDS the BPQA contact the National Institute of Health's Office of Alternative Medicine, the American Holistic Medicine Association, the Fetzer Foundation, or any similar recognized organization or certified board for the names of peer review who are personally unknown to the member being evaluated.

The factual basis for this recommendation is not apparent from either the data presented to the Commission or the final report, nor is it clear how the recommendation fits into the charge by the General Assembly. Indeed, the subject of peer review was raised impromptu by certain members of the Commission, who surmised that physicians are often afraid to discuss complimentary medical methods with patients, presumably because peer review of a complimentary medical practice is usually conducted by practitioners of traditional medicine, unfamiliar with methods used in such a practice. However, the Commission presents no data supporting the existence of a "chilling effect" on physician recommendations for complimentary medical care. Furthermore, the Commission neither gathered nor presented data concerning the peer review process currently carried out under BPQA's authority.

As indicated above, the Commission inferred that apprehension of disciplinary action resulted in reluctance by physicians to recommend complimentary medicine to patients. Those fears are unfounded. BPQA has never taken disciplinary action against a physician licensed in Maryland for his or her use of complimentary medical methods. Where disciplinary action has been taken against self-styled practitioners of complimentary medicine, it has resulted from either a violation of medical standards independent of the use of complimentary medicine or failure to use appropriate informed consent.

BPQA employs a single standard for testing the competency of a medical practice. All physicians, whether practitioners of traditional or complimentary medicine, as holders of Maryland medical licenses, are uniformly held to that standard. While practitioners of traditional and complimentary medicine by definition diverge in treatment, both are expected to engage in proper medical inquiry, including performance of an adequate history and physical, to arrive at a diagnosis and prescribe suitable and effective treatments, to fully document the practitioner's thought processes in the medical record, and to engage in appropriate informed consent. A physician who complies with these guidelines has little to fear with regard to potential disciplinary action, regardless of whether the treatment provided is deemed "traditional" or "complimentary."

Peer review is a customary and established method of assessing a medical practice whereby experts in the involved medical specialty determine whether the practice meets appropriate medical standards. In Maryland, disciplinary action based on violations of medical standards is based on peer review. Physician peer reviewers are selected from a pool of specialists in specific areas of medical practice. Selection of reviewers is typically straightforward, based on the specialty definition promulgated by the pertinent specialty board. At present, there is no recognized specialty board for complimentary medicine and

any physician, no matter what the training or credentials, may be self-described as a practitioner of complimentary medicine. It should be noted, however, that acupuncturists and chiropractors, both generally deemed complimentary health care providers, are respectively regulated by the Maryland State Acupuncture Board and the Maryland State Board of Chiropractic Examiners.

As licensed physicians, practitioners of complimentary medicine fall under BPQA's regulatory authority. However, the question arises of how to peer review these physicians when, by their own definition, their practice is distinct from traditional medical practice. While it is understandable that a complimentary practitioner would prefer to be reviewed by a physician totally sympathetic and exclusively oriented to that type of practice, the resultant risk is lack of objective review. Indeed, in no other type of peer review is the respondent physician permitted to tailor the review to his or her specific requirements. Typically, complimentary practitioners function as primary care physicians and, in the peer review process, are evaluated as such.

In its conclusion, the Commission quotes Sir William Osler: "[m]edicine is a science of uncertainty and an art of probability," and states that "Maryland should encourage creativity in medicine that results in good outcomes, prioritizing health and preventing disease." However, this counsel should not be without limits. A fundamental precept of physician peer review is the recognition that the art of modern medicine is built on a foundation of scientific method, thought, and education.[1] Purely subjective methods of treatment and evaluation of medical practice cannot be adequately substituted, at least not under the auspices of a medical license nor in a regulatory framework designed to protect the public health and safety. Historically, the Maryland General Assembly has recognized the need for regulating physicians as members of a learned profession invested with a recognized degree of training and skill. Indeed, the dangers inherent in untested medical treatments are too great to permit purely consumer-driven

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[1] The undersigned members of the Commission also express concern regarding the conclusions of the efficacy of certain complimentary treatments targeted in the Final Report. The Final Report concludes that certain complimentary methods may be more effective than traditional treatment modalities. However, this conclusion is unsupported by extensive clinical examination. As a result, the effectiveness of those treatments remains largely anecdotal. The attached article entitled "Analysis of Homeopathic Treatment of Childhood Diarrhea" from Pediatrics, Vol. 96, No. 5, November 1995, illustrates the limited nature of the type of scientific methodology frequently employed to promote the use of complimentary medical treatments.

mandates.[2] The current regulatory framework as established by BPQA provides a rational and balanced means by which consumers can be assured of receiving competent medical care from providers of both traditional and complimentary medical treatments.

It is the conclusion of the undersigned members of the Commission that there is little need for legislative involvement in either the education or peer review of Maryland physicians. The former is under the aegis of Maryland medical schools based on national standards for medical education. The latter is sufficiently addressed through BPQA's recognition of consumer demand for complimentary medicine and disciplinary activity focused solely upon the physician's underlying medical practice, and not the use of complimentary treatments. Such an approach serves to protect the public from incompetent practitioners, while, at the same time, does not restrict consumer access to complimentary medicine.

Respectfully Submitted by:

Sidney B. Seidman, M.D.
John F. Strahan, M.D.

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[2] See accompanying articles entitled "Bitter Herbs: Mainstream and Menace," annals of Internal Medicine, Vol. 121, No. 10, November, 1994, and "Mystery Cures," consumer Reports, Vol. 60, No. 11, November, 1995.

Bitter Herbs: Mainstream, Magic, and Menace

If nothing else, politicians are often the quintessential pragmatists. I recently asked a German legislator why his country's national health plan pays for homeopathic and other "unscientific" therapies. His reply was simple. "I can't prove they work, but many swear by them. They seem often to replace our doctors' expensive evaluations and tests and, so far as I know, they are safe."

In the United States, such remedies attract an enormous and growing number of patients. Their use is so extensive that a 1990 survey suggests that there are, in effect, two parallel tracks for those seeking primary care (1). The first offers "scientific medicine." Focusing on services by internists, family physicians, pediatricians, and obstetrician-gynecologists, it is heavily regulated—some feel over-regulated—by governmental and other bodies. The second is often called "alternative care" and is provided by massage therapists, acupuncturists, homeopaths, megavitamin therapists, herbalists, and others. It is largely unregulated. People explore each path with equal frequency and often travel on both, spending lots of money as they go (1). It is difficult to estimate, however, whether expenditures on alternative care save money for the United States. Would we spend more or less if such therapies were not available?

There is ample evidence that physicians practicing scientific medicine can be dangerous for patients. So, too, with alternative offerings, and Woolf and colleagues (2) provide a good example of this in this issue. Until recently, a Chinese herbal product, "Jin Bu Huan Anodyne Tablets," was available not only in health food stores but also in the growing number of pharmacies trumpeting the virtues of "natural" remedies. Unregulated, the tablets sat next to medicines that had survived regulatory oversight. Produced by a "drug manufactory" in China, the package insert in the box asserts that the tablets are "good for anodyne, sedative, spasm and hypnotic." It warns, however, that a transient "sleepy state, little dizziness and felt strengthless or nausea . . ." may occur. But now strong evidence exists that Jin Bu Huan may injure the livers of some adults (2). Children, too, may be hurt if they ingest these pills accidentally (3). As a result, long after the tablets became widely available, investigators from the Food and Drug Administration (FDA) have taken steps to remove them from consumer outlets nationwide (4).

Why is there exploding use in the United States and other developed countries of what many term "unscientific medicine?" Do its benefits outweigh its risks? And, given risks, how will they be addressed at a time of antiregulatory, antigovernment sentiment? I suspect that the turn toward unscientific medicine reflects two different but synergistic impulses. The first is deep yearning for cherished and affordable aspects of the good old days, with particular note of their more leisurely pace. The second is growing confusion and disenchantment over expensive scientific medicine, with its mixed messages and unfulfilled promises.

In today's frantic and increasingly impersonal world, replete with fax machines, voice mail, the tortuous information highway, and the bewildering technologies of medicine, people find hope in recreating the past. The "original instrument" movement in music, the renaissance of the portrait painter, the fascination with Wharton's *Age of Innocence*, and the urban dweller's flight to the country represent point-counterpoints to the suffocation that comes from today's headlong rush. And the countervailing simplicity, clarity, and directness that patients seek may be represented by a tablet or potion derived from an exotic "natural" herb.

At the same time, clinical trials investigate scientific medicine with increasingly sophisticated techniques that proliferate, confuse, and too often disappoint an avid audience. Methodologists who develop and critique their design and findings wield more and more complex tools. How many approaches to multiple regression now exist? Which statistical inference is right for the latest set of data? In 1994, is butter or margarine safer? When do you remove, radiate, or watch prostate cancer? Is lumpectomy for breast cancer really as safe as more mutilating surgery? What's best for back pain? So, even at a time of rich scientific endeavor and discovery, patients turn to plants or homeopathic distillates and announce, "I would rather swallow this! It's pure, it's safe, it's magic, and it will help me face the world."

But now their purity, safety, or magic also comes into question. The contents inside the Jin Bu Huan box, for example, are not Jin Bu Huan; the manufacturers either used the wrong plant or got it wrong on the label. Moreover, the safety is suspect; its effect is not magic alone. The ingredients have a pharmacologic effect that may help or hurt the patient, depending on the total dose and individual susceptibility (2).

How should the benefit that may come from alternative therapies, whether through the placebo effect or beyond, be maximized? And how should the dangers of these therapies be minimized? With respect to the benefits, the multibillion dollar industry that produces and promotes many of the therapies is not shy about extolling their putative virtues. As has been true in the United States since its founding, proponents of alternative therapies find it easy to attract the public's attention (5). The popularity may grow through future clinical trials that show efficacy, and interest in such trials is increasing. Small-scale experiments are sponsored by the highly visible, albeit modestly funded, Office of Alternative Medicine (OAM), established at the National Institutes of Health (NIH) "to encourage the investigation of alternative medical prac-

tices, with the ultimate goal of integrating validated alternative medical practices with current conventional medical procedures" (4). Larger trials are funded with less fanfare through other branches of the NIH. Private philanthropies, led by the Fetzer Institute in Kalamazoo, Michigan, are investing aggressively in this area. All this activity likely represents a response to public demand and a carefully orchestrated effort to engender interest.

Minimizing hazard is the principal responsibility of the FDA, whose job is "to see that the food we eat is safe and wholesome ..., the medicines and medical devices we use are safe and effective ..." (6). Until now, the FDA has insisted that before it may be made widely available, a "product is studied scientifically in properly controlled trials, so that we can know whether it works for a specific purpose and so that patients are not exposed to experimental products of no proven value" (4). The FDA is working with the OAM to initiate trials that test everything from shark's cartilage, touted as a treatment for cancer, to "Dr. Revici's treatment and Bee Pollen products" (4). But the number of such products already for sale is staggering. What should come off the shelves until efficacy and safety are documented?

The lobby for alternative therapies is powerful. This October, Congress passed "The Dietary Supplement Health and Education Act of 1994." The measure has been cleared for White House approval, and as of this date, President Clinton is expected to sign it. Despite conciliatory rhetoric announcing a compromise, the law, skillfully shepherded by Senator Hatch, represents a defeat for the FDA and a victory for those promoting alternative therapies. It may well become known as the "loophole act"—its language is so imprecise that we may soon find even more trucks filled with scientifically suspect substances driving unchallenged to the store or pharmacy. The language shows lawyers hard at work, establishing a rather fine distinction between reducing risk and helping to maintain a healthy body. Claims for risk reduction are now reserved for substances that are reasonably well-established scientifically, such as calcium for osteoporosis. But, as people strive to maintain health, an elixir containing an amino acid can now be advertised as boosting the immune system. The law may make it more difficult for the FDA to proscribe products such as Jin Bu Huan in the future. And, in a step characteristic of politicians who know they are facing matters complex and politically hazardous, Congress dances around the issue of health claims for substances such as herbal products by establishing a Presidential commission to study what to do with them in the future. For now, the laws of the land pose few obstacles for alternative therapies. When they are dangerous, we will learn so primarily from reports of those who were harmed by them.

As alternative therapies proliferate, what role can physicians play in addressing a phenomenon that, at first glance, seems to fly in the face of scientific medicine? First, one should remain humble about physicians' own mixture of art and science. Not so long ago, leeches and frozen stomachs were in their domain, and many of their beliefs today must remain tentative. Second, physicians should learn more about alternative therapies. They need to understand what they are, who uses them, and when. Third, physicians can apply their rich scientific heritage to put alternative therapies to the test. Fourth, they can promote open communication with patients who seek help from both tracks of medicine. In so doing, physicians will gain more insight into the effect of alternative therapies and may help discover and prevent those dangers that exist. And finally, physicians should consider whether the current fascination with such therapies derives, in part, from their growing failure to practice personal medicine. Our citizens cry out for attention. Physicians should work with them, and within medicine, to claim more time for the human interactions that are central to the physician-patient relationship. This may come at the expense of some tests and procedures. It will be well worth the tradeoff.

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SPECIAL ARTICLE

Analysis of Homeopathic Treatment of Childhood Diarrhea

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The article entitled "Treatment of Acute Childhood Diarrhea With Homeopathic Medicine: A Randomized Clinical Dual in Nicaragua" by Jacobs et al (*Pediatrics*. 1994;93:719–725) reported a study of the efficacy of homeopathy in the treatment of acute childhood diarrhea. Children with diarrhea were entered into the study if the diarrhea was not severe (type C severe diarrhea patients were sent to a hospital). Oral rehydration therapy was begun, and subjects were randomly assigned to receive either homeopathic preparations or placebos. The preparations were determined by a computerized therapeutic scheme. This scheme depended on a family observer's answers to questions from an "experienced homeopathic practitioner." The article purports to show a statistically significant difference favoring the treatment group over the controls. The report has faults of 1) purpose, 2) method, 3) diagnosis and treatment selection, 4) results interpretation, and 5) authors' editorial comments. The reported difference between treatment and control groups are of dubious significance. This article argues that the study's conclusion that homeopathy is effective for childhood diarrhea is unwarranted.

Homeopaths claim that homeopathy is an "alternative" medical system. The authors justify their research in the hope that homeopathy would have public health importance. If true, one would presume the system to be equal to or better than oral rehydration therapy. Therefore, even if it were positive, this study would not prove homeopathy to be an alternative to the standard treatment of childhood diarrhea.

METHODS

Government agencies do not routinely assay homeopathic products. Homeopathic products have been found to be adulterated with active material.[1–3] This study did not report precautions against adulteration of the experimental material nor assay the products after production.

Some homeopathy experiments have been erratic and poorly controlled.[4] Conclusions have been inappropriate and incorrect.[4,5] Because of these problems, and the extraordinary concepts and claims of homeopathy, the methods of a study should be nearly faultless and results should be reported cautiously.

All materials were stated to have been diluted to 30C "potency," representing a concentration of 1×10^{-60} beyond the original concentration. But the original concentration is not given (and usually is not given in homeopathic preparations) so that the "potency" (the dilution beyond the native concentration) is not meaningful.

The diagnostic system was unvalidated and unreliable. A diagnostic scheme or algorithm should yield consistent results among those who use it; histories should give reliable information, and physical signs should be consistent among observers. This homeopathic diagnostic scheme used an unproved classification for each combination of symptoms and signs. Such methods are part of homeopathic practice, which depends largely on the therapists' subjective impressions. Although computerization of the observers' impressions in the study gives an appearance of standardization, the symptoms given for each treatment selection were overlapping. There was no assurance that different observers would have have given consistent descriptions of the same patient.

For instance, the odor of rotten eggs was in three of the six symptom complexes used to select one of the six homeopathic examples in Table 1 (page 721) (eighteen different materials were actually used). Odor may not be either present or absent, but may vary in intensity and with time. Detection depends on the observer's genetic olfactory sensitivity, acquired alterations (viral infection, presence of other odors, sensory organ fatigue, memory, and the time of observation.

Diarrhea worse at night or after midnight was in three choices. The time when diarrhea is described as worse depends on how often one sees stools, diapers, witnesses the child defecating, and how often one arises at night to observe. Whether a child is "fussy" or "lethargic" depends on the time of observation.

Thus, the homeopathic diagnosis was determined by a short snapshot in diagnostic time. Had the evaluation occurred 12 hours before or after, the diagnostic category could easily have been different. Because the authors cite no published data on this diagnostic scheme showing consistency among observers, the diagnostic categories cannot be considered to be reliable. Although some of this problem might have been neutralized by use of the control group, any outcome differences between the two groups might more likely be due to unmeasured confounding factors.

Although there was a protocol for measuring stool frequency, it seems to have been designed for adult self-observation, not for observing another person, and was adapted to children for this study. Judgment as to whether a stool was formed, the frequency of diaper changes, the number of nocturnal observations, etc, could have biased the recording.

The treatment selection process had dubious reliability since the preparation was selected based on symptoms and signs that existed at the time of interview, and was continued through the rest of the illness, regardless of subsequent symptom changes. In addition, there was no reference indicating that the eighteen materials were individually effective.

RESULTS AND INTERPRETATION

The authors admitted that using a multiplicity of preparations, tailored to the individual's symptoms presented "an inherent methodological problem," because "most clinical trials evaluate the effects of a specific medication." This "inherent methodological

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problem" could have been solved by planning in advance to evaluate one specific treatment in the cohort of children who qualified for it. The meaning of the statistical test results in this study are unclear because the test was applied to aggregated, nonuniform data.

The authors state also that it was "our intent to evaluate the system of homeopathic treatment . . . ," but the authors evaluated a variety of treatments for several different disorders that shared only one common symptom, diarrhea, while the treatment selected was based on a multiplicity of symptoms and findings, using an unproven diagnostic scheme and decision method (page 720). The results cannot be generalized to other disorders, other situations, or to other practitioners.

The mean number of days to fewer than three unformed stools on 2 consecutive days was 3.0 for treated and 3.8 for untreated patients, but the standard deviations were 1.9 and 1.7, respectively. These are wide standard deviations for a small difference, and suggest the need for examination for outliers and diminish confidence that the results were significant.

The report showed *P* values for four diarrhea indicators plus the weight/height percent change. Statistical significance was borderline, with *P* values of .048, .036, .054, .037, and 0.30. Three barely made statistical significance and two did not. All were direct or indirect measures of the same phenomenon—diarrhea. To a critical eye these values are not impressive, and a repeat study under the same conditions could easily show negative or opposite results.

The authors stated that the number of days of diarrhea before entry was not different between the two groups. But Tables 6 and 7 (page 723) contained a number of unexplained discrepancies. There are three types of errors in the tables; 1) recording and computation, 2) stratification, and 3) pooling of results.

Recording and Computation

First, although the unadjusted 2 × 2 table indicates 40 subjects in the treatment group, the sum of the subgroups recorded in each stratum is 39. Second, although the sum of the numbers of subjects in the second stratum is shown as 19, the two subgroups are shown as 6 and 16, which equals 22. Third, the odds ratio and 95% confidence interval for the second stratum are presented as 4.33 and 1.01 to 19.6, respectively. The correct values given the cells presented are 4.95 and 1.2 to 23.30.

Table 7 (page 723) indicates a total of 71 patients whose stools were collected for culture and parasite examination although the text states 74. One wonders what other errors might have occurred in recording the results and how they affected significance.

Stratification

The strata in Table 6 (page 723) are either mislabeled or classified arbitrarily. The second stratum is labeled "Prior days >1, <5." The third stratum, labeled "Prior days >4." should presumably have been labeled as >5. The number of subjects in each stratum is uneven, with the strata containing 14, 20, and 5 treatment patients, respectively. No reason is given for this uneven grouping. It is not clear how this grouping effected the results.

Although the authors indicated that they used the program, Epi-Info (USC, Inc, Stone Mountain, GA) for data analysis, they did not report a test for homogeneity among the groups. Homogeneity testing is necessary when the stratum-specific odds ratios are discrepant. The Mantel-Haenszel calculation depends on homogeneity across strata.

Table 7 (page 723) shows that children with specific pathogens found in stool were benefitted, whereas those without identified pathogens were not benefitted. The *P* values in this table were more significant for the same categories as listed in Table 6 (page 723) (.006, .034, .003, and .006.) The text offered no explanation.

One must consider the presence of active antibiotic and/or anti-parasitic material (adulteration) in the "homeopathic" preparations to which the treatment group is claimed to have responded (see below).

Pooling of Results

Table 4 (page 722) shows the numbers of children treated with each preparation. Eighteen different homeopathic preparations were administered. The treatment and control numbers are unbalanced by a difference of 50% or more for seven of the eight compounds listed. For instance, eight were treated with chamomilla with five controls. Five were treated with calcarea carbonica but there were only two controls. Three were treated with "other" methods, but nine were given controls pills. This imbalance created an aggregation of noncomparable groupings. As stated above, all diagnostic and 18 treatment groups were lumped together for analysis (Table 4). If only one or two treatments were effective, and the others were not or showed only a slightly positive trend, the sum of the results might be positive, but one could not determine which treatments were effective, and which were not. In practical terms, in a diarrhea epidemic, one would not be able to select effective treatments. Also, the calculated means of treatment and control subjects as shown in the Figure (page 722) become meaningless.

Statistical and Clinical Significance

Even if the objections above did not exist, there was no statistical significance between treatment and control groups in terms of the mean number of unformed stools at treatment days 1, 2, 4, and 5, as shown in the Figure. There was statistical significance at day 3, but looking at the different days individually inflates the actual alpha, or the probability of type I error.

In addition, the study's results were not clinically significant. The homeopathy group had on average less than one stool per day (3.7 vs 2.8) at day two, and a difference of one stool per day (3.1 vs 2.1) at day three, the times of maximum difference. A difference between three bowel movements and two bowel movements per day is not significant clini-

cally, especially when one considers that there was no difference between the two groups in the first 24 hours.

As mentioned above, a few outliers could have altered the outcome. Only the means of the number of stools per day were presented in the Figure; the individual ranges of points on the curves were not shown. If a few outliers caused the overall difference, the large majority of children would have shown no benefit.

Authors' Commentary

The authors made numerous statements that were not warranted from the data presented and from previously published papers. They note: "... there is no scientific explanation for the mechanism of action of homeopathic medicine..." The statement assumes that homeopathic medicines have an action. Evidence for homeopathy effectiveness is poor and conflicting (see below), and reasonable laboratory evidence for effect does not exist. This study does not support the assumption.

To support their contention, the authors refer to a mechanism of action in a discredited paper, the Davenas–Benveniste basophil degranulation experiment.[6] That report claimed that "solutions" of immunoglobulin E (IgE) diluted to 10^{-60} and 10^{-120} caused as much or more degranulation of basophilic blood cells (histamine release) as did the original solution at 10^{-3} concentration. The clinical implication was that homeopathic preparations of IgE would be effective for asthma or hay fever. The work was deflowered in a series of articles[4,5] and experiments that failed to reproduce its results.[7,8] One of the negative experiments was performed in the original laboratory under better controlled conditions than for the initial runs.[2] Another analysis[5] of the original report's data showed that: 1) effects of the homeopathic preparations were unreproducible from one trial to another, and 2) if the original data were to be believed, homeopathic preparations were more likely to worsen the condition by releasing just as much histamine as when undiluted. This paper does not mention these articles.

This article repeats a misunderstanding of the 1993 *New England Journal of Medicine* (Eisenberg et al) study on the prevalence of "alternative" medicine usage in the United States.[9] It states that ">30% of the United States population had used alternative medical practices to treat serious medical conditions..." Although the subjects in that study were asked if they had a serious disorder in the previous year, the subjects did not state, nor did the report record, that 30% used "alternatives" for those serious conditions. (It is hard to believe that 30% of the United States population has "serious medical conditions"). That study also created its own definition of "alternatives," as those subjects not commonly taught in medical schools or covered by insurance. Yet its "alternatives" also included adjuncts to biomedicine such as weight loss clinics and group psychotherapy. The Eisenberg study did not reflect the prevalence of "alternatives" as commonly perceived, but reflected the definition by its authors.

This article also quotes a 1991 meta-analysis of homeopathy studies[10] as finding that 15 of 22 (sic) "well done" studies were positive. The actual wording of the meta-analysis was that 23 were the "better studies" of the 107 found.[10] But it stated that all studies were generally "of poor methodological quality," and "disappointing." Only 23 of 107 homeopathy trials scored 55 or higher out of a possible 100 points, and only seven of them scored 80 or higher. Only three homeopathy trials out of 107 presented a statistical power conferring reliability. Two of those three studies were negative. The meta-analysis did not evaluate controls for adulteration. Nor did it score papers for the magnitude of standard deviations. The meta-analysis and one other both concluded that homeopathy probably had no more value than a placebo.[10,11]

This article made inappropriate conclusions to the public health significance of the study. It states that: "Acute diarrhea is the leading cause of pediatric morbidity and mortality world-wide. In the developing world there are 1.3 billion episodes of diarrhea and 5 million deaths each year from this illness..." But a public health impact is not suggested by this study. Children with severe diarrhea were excluded and sent to a hospital. Only children with lesser degrees of diarrhea were included; there were no fatalities, and all recovered spontaneously, including the controls. In addition, there was no difference between the two groups for the first 24 hours of treatment when diarrhea was most severe. The authors' statements inflated the magnitude of the problem that homeopathy would supposedly solve.

The authors nevertheless state: "Acute childhood diarrhea [is] ideal for ... homeopathic trial because ... no standard allopathic [sic] treatment would have to be withheld and ... the public health importance ... is great." There is no explanation for how there could be great public health importance to a self-limited mild disorder that resolves spontaneously in 4 days.

The authors state that "The dilution of homeopathic medicines to infinitessimal [sic] doses has led many scientists to reject homeopathic theory..." The homeopathic dilution used in this study (and commonly present in marketed "solutions") was 10^{-60}. At 10^{-24} concentration, there is only a 50% chance that one molecule remains. At 10^{-60}, the chance of one molecule being present is 1 in 10^{-37}. Homeopaths developed the ad hoc theory that water molecules somehow become rearranged and "remember" the solute's essence and mimic its action.[6] If that were the case, then the "solution" should retain every action of every molecule that was in the preparation at the beginning of the "potentization." That would amount to a nearly infinite number of actions (including that of any alcohol present), but homeopaths do not explain why the claimed actions are only those of the material on which they focus. At 10^{-60}, it is more likely that there would be a molecule of the River Jordan water rather than a molecule of the material in the original solution. Thus, one might just as well ascribe the "effects" of homeopathic "solu-

tions" to that of a religious miracle as opposed to rearranged water molecules.

In addition, if the theory were true, then water molecules could transmit the "essence" or "energy" to one another in the absence of the original material, because after a dilution of 24×, no original molecule would likely be present, even of the original water solvent. That means that striking the solution container against the hand ten times (or its modern counterpart, a mechanical vortex) is able to transmit the original "essence" from water molecules to water molecules with nothing else present. It is an understatement to say that "many scientists" reject homeopathy. The number is near unanimity.

DISCUSSION

The null hypothesis must be brought into bold relief in homeopathic research because of the implausibility of its claims. Researchers should display beyond reasonable doubt that their observations are not the result of error, unconscious bias, tampering, or misinterpretation.

This article raises three major questions. First, are homeopathic preparations effective—in this case, in childhood specific and nonspecific diarrheas? Second, if they are effective, what mechanisms could explain effectiveness that is consistent with laws of chemistry, physics, and pharmacology? Third, if homeopathic remedies are effective, do they work as well as or as cheaply as known remedies developed in rational biomedicine?

Homeopathy proposes that medical disorders can be cured by using materials that produce the same symptoms that the subject has ("Similia similibus curantur"–like cures like.) It proposes that extraordinary dilutions ("law of infinitesimals") of the material, after a specific type of mixing, "potentizes" (strengthens) the "solution." "Potentizing" occurs by a succession of 1:10 (X) or 1:100 (C) dilutions with "succussion"–a repetitive jarring or mixing of the "solution."[12] Although part of homeopathy practice involves "proving"—a series of empirical trials with successive dilutions to find the right "potency" for each illness—this study used an arbitrary "potency" of 30°C (or 60X). No reason was given for selecting 30°C (60X) "potency" rather than any other.

The proper "potency" is claimed to require extensive consultation along with the "provings." This method would not be practical for treating an acute illness like childhood diarrhea, especially for a large number of children in one area. Instead, this trial used a questionnaire and a computer-derived treatment decision. There is no evidence in scientific literature that the diagnostic scheme is reliable, that the data fed to the computer or its program have any validity, or that the treatments selected by the computer are appropriate.

As shown above, the data in the tables and those in the text were incorrect and/or inconsistent. The data analyzed consisted of a number of different diagnostic categories and eighteen different treatment materials, all lumped together for analysis. One cannot determine from this presentation which of the diagnostic categories or which of the treatments were effective and which were not. It is entirely possible that none was effective, or that one or two were effective and the others were ineffective—the data presented could not distinguish. Because the crude data were not presented, and only the mean values for the treatment and controls were given, one could not determine if the results were attributable to only a few in each category who benefitted. In addition, the standard deviations were so wide in both the treatment and control groups that there is little confidence that the results are truly significant.

There was no precaution against adulteration of the homeopathic materials or analysis of the materials for active substances. The result showing greatest treatment effectiveness for children with known pathogens was unexplained, but could be explained by the presence of effective medication in the treatment product, perhaps unknown to the experimenters and their agents.

The public health consequence of using homeopathy could be opposite to that predicted in the article. If parents were to use ineffective homeopathic remedies for children with severe diarrhea, there could be unnecessarily prolonged illness and unnecessary death. Although public interest in homeopathy may be less than that implied in this article, it is probably significant. One estimate of homeopathy product sales in the magazine, "Health Foods Merchandiser" is $200 million/year.[11] Homeopathic over-the-counter products are heavily advertised in health magazines.[11]

In summary: 1) The study used an unreliable and unproved diagnostic and therapeutic scheme; 2) There was no control for product adulteration; 3) Treatment selection was arbitrary; 4) The data were placed into odd groupings without explanation, and contained errors and unexplained inconsistencies; 5) The results were not clinically significant and were probably not statistically significant; 6) There was no public health significance; 7) Selection of references was incomplete and biased to support the claims of the article, and references were quoted inaccurately; and 8) Editorializations were inappropriate.

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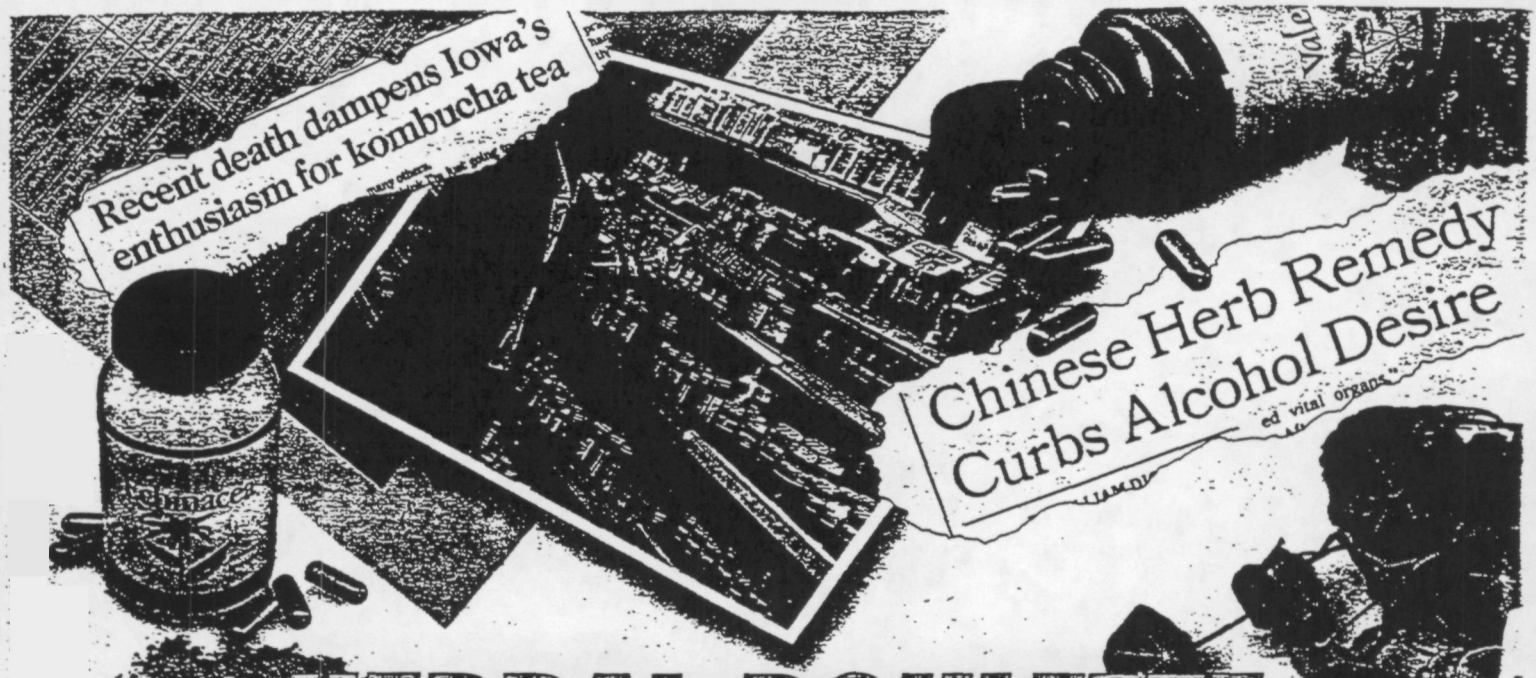


HERBAL ROULETTE

The makers of these 'natural' remedies don't have to prove they work, and they don't have to prove they're safe. You have to be very careful.

The bottles, lined up neatly on a shelf, promise botanical wonders from around the world: Bilberry extract. The fruit of cayenne pepper. Korean ginseng. Valerian root. Yucca stalk. Nearby hangs a laminated card, describing the benefits of each—dong quai root to normalize women's systems, milk thistle extract for healthy liver function.

The shelf, despite what you might think, is not in the back aisle of a health-food store. The products are lined up right next to the vitamin C capsules and calcium tablets at a brightly lit CVS store, part of one of the country's largest drugstore chains. And you could find similar products at your local SavOn, Thrifty, or Eckerd. Roughly one drugstore in ten now carries a large line of herbs; others stock at least garlic and ginseng.

Encouraged by widespread interest and greatly relaxed Federal laws, sales of "natural" herbal remedies are growing by an estimated 15 percent a year, and now total $1.5-billion, almost half the amount spent on "regular" vitamins and minerals. These products now are classified as "dietary supplements," a grouping that includes plant extracts, enzymes, minerals, and at least one hormone—the very popular melatonin.

The products range from ground-up herbs you probably never heard of (Kava Kava root) to nationally advertised brands (*Ginsana* ginseng and *One-A-Day* garlic.) The pills can cost $20 a bottle. Some consist of a single traditional medicinal herb, like *feverfew*. But others mix a handful: The ingredients of a supplement called *Up Your Gas*, a supposed energy-booster, include ginseng, spirulina, bee pollen, royal jelly, ma huang, guarana, wheat grass, gotu kola, and cayenne pepper.

Many people have good reason to be interested in plant products that might improve their health. A number of studies have shown that certain herbs may help people with conditions ranging from headaches to high cholesterol (see "Herbs that Might Help," page 700). Some supplements might even have the potential to become the next quinine, aspirin, or digitalis—all drugs that were originally derived from plants.

But if you do decide you want to give herbal medicine a try, you face a formidable obstacle: The supplement marketplace is a shambles. There is no guarantee that the pills are what they say they are—and in most cases no one really knows what will happen if you take them. You have no way to be sure:

- ☐ Whether a plant's active ingredients, whatever they might be, have actually ended up in the herbal pills you buy.
- ☐ Whether a supplement's ingredients are in a form your body can use.
- ☐ Whether the dosage makes any sense.
- ☐ What else is in the pills.
- ☐ Whether the pills are safe.
- ☐ Whether the next bottle of those same pills will have the same ingredients.

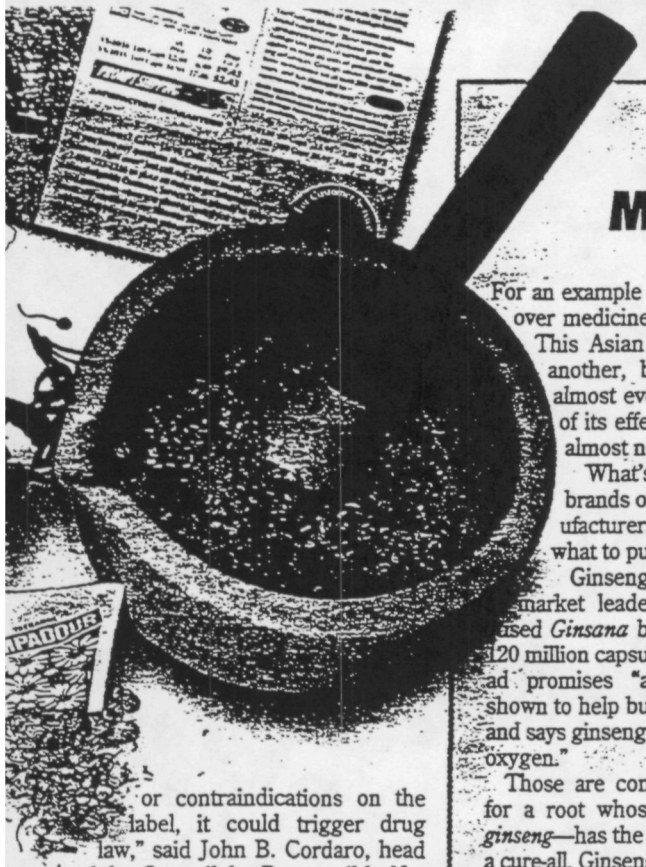
Even the manufacturers may not know those things; they're not required to do the testing or quality control that are routine for regular drugs. In this marketplace, it's hard to know what to trust. Varro E. Tyler of Purdue University, a leading expert in plant medicines, has written that much of what surrounds herbal medicine in the U.S. is "a minefield of hyperbole and hoax."

An unregulated market

This throwback to the days before drug standards and regulation comes to you courtesy of Congress, whose efforts last year to loosen up the regulations for traditional herbs have opened up a loophole big enough to be exploited by anyone with a pill-making machine and an eye for clever marketing.

For years the U.S. Food and Drug Administration did not quite know what to do about products like these. While prescription and over-the-counter drugs must be proven safe and effective, and foods need to meet manufacturing standards and be safe to consume, there was no place in the rule book for most plant products that claim medicinal effects; they fell somewhere between foods and drugs. So for decades there was an uneasy standoff. The FDA sometimes seized supplements on the grounds that they were unapproved food additives or unapproved drugs. But in general, the agency tolerated quiet sales of herbal remedies as long as manufacturers labeled them only as nutritional supplements and didn't mention medicinal uses.

"If a brand simply listed a dosage



or contraindications on the label, it could trigger drug law," said John B. Cordaro, head of the Council for Responsible Nutrition, a trade group representing the larger vitamin and supplement companies. Some manufacturers avoided that problem by simply giving their products suggestive names like "Sleep and Get Trim" and "PMS."

To promote their products, many manufacturers counted on word of mouth or on pamphlets about the medicinal benefits of various supplements—displayed nearby in the health-food store.

Then, in mid-1993, fresh from overhauling the nation's food labels, the FDA decided to turn to supplements—in 11 dense pages in the Federal Register, an "advance notice of proposed rulemaking." It was dry bureaucratese—peppered with reports of deaths, poisonings, and medical mayhem attributed to vitamins, herbs, and other supplements. The subtext: Stricter regulation needed.

That touched off a multimillion-dollar industry campaign urging Americans to "Write to Congress today—or kiss your supplements good-bye!" The country's 10,000 health-food stores became beachheads in virtually every Congressional district—with handbills, petitions, and discounts offered to letter-writers. Almost half of Americans take supplements, at least occasionally, so Congress was deluged—with four million letters and faxes, by one count.

The result—the Dietary Supple-

Photos by Whitney Lane

GINSENG

MUCH ADO ABOUT NOTHING?

For an example of the triumph of mystique over medicine, it's hard to beat ginseng. This Asian root has, at one time or another, been credited with curing almost everything. In reality, studies of its effects on humans have found almost nothing.

What's more, our own tests of 10 brands of ginseng suggest that manufacturers haven't even agreed on what to put inside.

Ginseng sales are booming. The market leader alone, nationally advertised *Ginsana* brand, now sells Americans 120 million capsules a year. A *Ginsana* radio ad promises "an all-natural supplement shown to help build energy and endurance" and says ginseng will "help your body utilize oxygen."

Those are comparatively modest claims for a root whose botanical name—*Panax ginseng*—has the same origins as "panacea," a cure-all. Ginseng has been called beneficial for stress, hypertension, ulcers, diabetes, atherosclerosis, depression, edema, impaired memory, anemia, and menopause. It's been dubbed a tonic, restorative, aphrodisiac, and life extender.

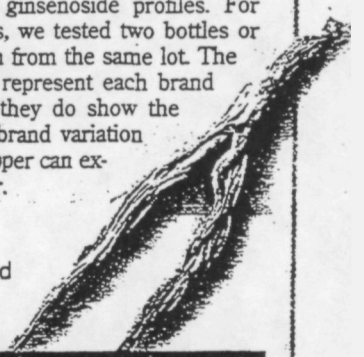
In the marketplace, confusion about ginseng abounds. *Nature's Resource* bottles say ginseng has been used for over 2000 years. *Rite Aid* says it's been used for over 5000. (What's three millennia among friends?) Some products say they contain raw root powder; others are extracts claiming an optimal balance of "ginsenosides," the root's supposed active ingredients. Still other products contain Siberian ginseng, which is an entirely different plant.

But evidence for ginseng's usefulness is scant. Many studies show that ginseng, often in big doses, affects small animals in interesting ways, but there's little human research—and most is not well controlled. One review calls ginseng "a medical enigma with no proven efficacy for humans." What about *Ginsana*'s claims? Thomas Peterson, an executive at the company that distributes *Ginsana*, told us the evidence is a secret. "It is not our policy to release any clinical support behind the product," he said.

But even if ginseng is good for your health, consumers face another hurdle: There's no way to be sure what's in a ginseng supplement. We measured the amounts of six ginsenosides in 10 different brands of ginseng. We found a wide variation, from brand to brand, in the pills' total ginsenoside concentration. Some pills had 10 or 20 times as much as others, and one brand had very little ginsenoside.

The labels don't help you tell what's inside. A bottle of *Natural Brand Korean* labeled "648 mg." had 10 times as much ginsenoside per pill as a bottle of *Naturally Korean* that also was labeled "648 mg."

Ginsana did appear to be standardized—single packages from each of three lots had nearly identical ginsenoside profiles. For the other brands, we tested two bottles or packages of each from the same lot. The results may not represent each brand nationwide, but they do show the sort of brand-to-brand variation in content a shopper can expect to encounter.



Inside ginseng Our tests showed that the concentration of total "ginsenoside," the supposed active ingredient, varied greatly among 10 brands of ginseng. Similar variation has been found in other dietary supplements.

Product (listed alphabetically)	Ginseng per capsule [1]	Ginsenosides per capsule [2]	Concentration [2] (percentage ginsenoside)
American Ginseng	250 mg	12.8 mg	
Ginsana (extract)	100	3.0	
Herbal Choice Ginseng-7 (extract)	100	6.5	
KRG Korean Red Ginseng	518	11.5	
Natural Brand Korean Ginseng	648	23.2	
Naturally Korean Ginseng	648	2.3	
Nature's Resource Ginseng	560	10.7	
Rite Aid Imperial Ginseng	250	0.4	
Solgar Korean Ginseng (extract)	520	10.6	
Walgreen's Gin-zing (extract)	100	7.6	

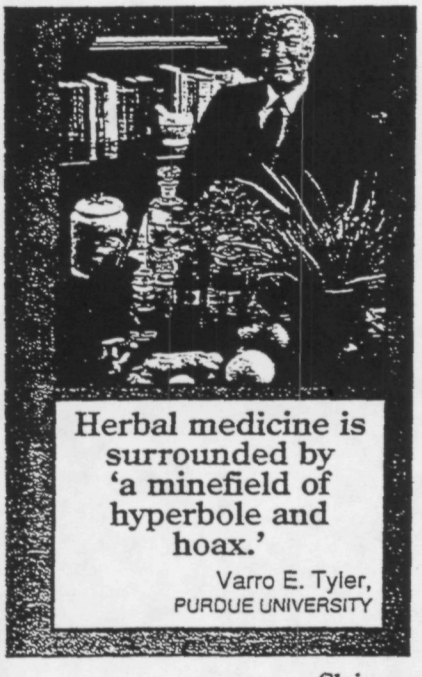
0 1 2 3 4 5 6 7 8%

[1] *According to label.*
[2] *Based on six major ginsenosides. Estimates for two other ginsenosides, if added, would boost totals only slightly and not change variation in concentrations.*

ment and Health Education Act of 1994—created a new category, distinct from food or drugs, that is nearly immune to the rules the FDA once used against questionable products. The new category is quite broad; it includes vitamins, minerals, herbs, amino acids, and practically anything else that had been sold as a "supplement" before October 15, 1994. There may be 20,000 such products; no one keeps count.

Here's what the law allows:

Products can go to market with no testing for efficacy. That skips the years-long, research-laden process that drugs are subjected to.



Herbal medicine is surrounded by 'a minefield of hyperbole and hoax.'

Varro E. Tyler, PURDUE UNIVERSITY

Companies don't have to prove that their products now on the market are safe. Before, a supplement maker had to prove its product safe if the FDA challenged it. Now the burden has shifted to the FDA, to prove the product *unsafe*. The maker must merely provide "reasonable assurance" that no ingredient "present[s] a significant or unreasonable risk of illness or injury."

Supplements need not be manufactured according to any standards. Federal standards—even the basics of quality control—won't be introduced for at least two years.

Claims are permitted on the packages. Supplements still may not claim to cure or prevent a *disease*, but labels may detail how a supplement affects the body's "structure or function," as long as claims are "truthful and nonmisleading." Thus, saw palmetto, an herb, can't be sold with the promise that it will cure an enlarged prostate, but the label may say it will "improve urinary flow" in older men—or say simply that it's "for the prostate."

Label statements might not have much evidence behind them. The new law simply says that manufacturers must have "substantiation" in hand. (That hasn't been defined.) And they need not show their evidence unless their label claims are challenged by regulators.

FDA approval is not needed for package or marketing claims. The label does have to say that any claims have not been reviewed or approved by the FDA, but that caveat can be in rather small type.

Though the new law has transformed the rules of the marketplace, few people know it. An analysis by the Congressional Research Service notes that consumers still believe "any product that appears in pill form has been reviewed for safety by the FDA, which is not true for supplements."

Even pharmacists may be confused. When our reporter asked the pharmacist at Duane Reade, a large local drugstore chain, about the value of St. John's wort (a nearby chart said it helped to fight depression), the pharmacist eyed the bottle, assured him, "It probably won't knock you out," and pronounced the contents safe. "It must be," she summed up: "If it's sold over-the-counter, it's FDA approved." Unfortunately, she was wrong.

Which herbs do what?

Marketing aside, it's difficult to find out which supplements even *ought* to help you. There is clear evidence supporting a few herbs and dismissing others. But in most cases the data are slim.

Many herbs have been promoted on the basis of anecdotal accounts, sometimes *centuries* of anecdotes—people attesting that a particular root, leaf, or berry has helped them. The problem with such accounts is that there is no way to tell what would have happened if the person had not taken the remedy. Most ailments are self-limiting. And many more cases are susceptible to the placebo effect: You may feel better as long as you *think* you've taken medicine.

To distinguish real efficacy from the placebo effect, FDA-approved drugs have to rely on the consensus findings of several proper clinical trials. The gold standard of such research is the randomized, double-blind trial. Participants are assigned either to take the drug under study or an ineffective placebo. The study is "blinded": Neither participants nor the researchers are told who got what until the study ends, to rule out any possibility that suggestion might influence the results.

Few supplements can meet that standard. There's little economic incentive for manufacturers to bankroll new studies—you can't patent an herb, to recoup the costs.

No matter how shaky the evidence, supplement makers and pro-

HERBS THAT MIGHT HELP

Anyone who's soothed a toothache with oil of cloves or been jolted to life by coffee knows that plants offer powerful medicine. But with dubious claims being made for so many herbs, some proponents fear the truly promising herbs may be overlooked.

Here are 10 herbs for which there is reasonably strong evidence of beneficial physiological effects, and which appear to merit further study. The list is based on the work of two respected and prominent "pharmacognocists" (specialists in plant medicinals)—Varro Tyler of Purdue University and Norman Farnsworth of the University of Illinois—and on other published medical research.

This is not a recommendation that you buy and use these products. While some—like chamomile and ginger—are innocuous, others should not be relied on for regular medical treatment. Hawthorn, for instance, is no substitute for established heart-disease therapy.

HERBS THAT CAN HARM

The U.S. Food and Drug Administration has identified a number of herbs that can cause serious harm. Some, including these five, are still being sold under various brand names.

Chaparral Sold as tea, tablet, and capsule and promoted as a blood purifier, cancer cure, acne treatment, and natural antioxidant. Has caused at least six cases of acute nonviral hepatitis (rapidly developing liver damage) in North America; one patient required a transplant. Sometimes an ingredient in combination-herb formulas.

WINNERS AND LOSERS IN THE WORLD OF PLANTS

Chamomile Used for indigestion. The tea, from tiny flower-heads, may suppress muscle spasms and cut inflammation in the digestive tract; it's used for menstrual cramps as well. (Topically, chamomile oil or ointment may be applied as an anti-inflammatory, for skin and mucous membrane problems.) A volatile oil is mainly responsible, so the tea must be made from fresh herb—fresh smells like apples; old, like hay—and steeped long enough to release the oil. People allergic to ragweed or flowers in the daisy family could suffer reactions.

Echinacea Used as an immunity booster. Also in the daisy family, this herb was sold as a drug before antibiotics existed. A few controlled trials suggest it can increase resistance to upper respiratory infections, perhaps by stimulating certain white blood cells. Benefits may be lost with continued use, however. May cause reactions among people allergic to the sunflower family.

Feverfew Used for migraine headache. Chewing the leaves is a folk remedy, but may cause mouth sores. A double-blind British study has suggested that feverfew taken daily can cut the occurrence of attacks by one-fourth.

Garlic Used for high cholesterol. Considering only the best-designed of numerous studies, a 1993 analysis showed that the equivalent of one-half to one clove daily could lower cholesterol an average of 9 percent; a similar 1994 "meta-analysis" gave stronger results. It might not work for all people, however. Enteric-coated pills, which dissolve in the intestine, cut odor and improve the absorption of allicin, apparently a key ingredient. Too much garlic can hinder blood clotting, so people on anticoagulants should be wary.

Ginger Used for nausea. Double-blind research shows that taking ginger before traveling can prevent motion sickness. This root can quell other nausea as well. Crystallized ginger, a confection sold in Oriental food markets, works too. No side effects have been noted with therapeutic dosages, but there's potential to inhibit clotting.

Ginkgo biloba Used for circulation. Enhances blood flow to the brain, according to a review of several published studies. For the elderly, that supposedly can improve concentration and memory, absent-mindedness, headaches, and tinnitus, a ringing in the ears. May also aid circulation to legs, to relieve painful cramps.

Hawthorn Used for heart disease. Substances in the fruit, leaves, and flowers dilate blood vessels and lower blood pressure. It relaxes smooth muscle in coronary vessels and thus may help avoid angina. Should not be used without consulting a doctor.

Milk thistle Used for liver damage. This plant's small, hard fruits have been shown to protect the liver against a variety of toxins. Human trials called "encouraging" for hepatitis, cirrhosis. Standardized extracts concentrate silymarin, a substance that apparently prevents the membrane of undamaged liver cells from letting toxins enter. Should not be used without consulting a doctor.

Saw palmetto Used for enlarged prostate. Was prescribed for a variety of urogenital ailments until 1950. Several studies suggest the extract can improve urinary flow in men with benign prostate enlargement. Also shows anti-inflammatory effects. Slows conversion of testosterone into a more active form that enlarges the gland.

Valerian Used for sleep problems. May have mild sedating and tranquilizing effects. Probably depresses brain centers and relaxes smooth muscle directly. May be used as tea, tincture (alcohol-based solution), or extract in capsules. The most unpleasant aspect may be its odor, like old socks or sharp cheese.

Comfrey Sold as tea, tablet, capsule, tincture poultice, and lotion. In the past decade, comfrey taken orally has been linked to at least seven cases of obstructed blood flow from the liver, with potential for cirrhosis (scarring); one person died. A woman's drinking comfrey tea when pregnant is suspected in her newborn's liver disease. Animal studies show lung, kidney, and gastrointestinal problems are also possible. Four countries (Australia, Canada, Germany, and Great Britain) restrict comfrey's availability.

Ephedra Also called ma huang and sometimes epitonin. Contains the stimulants ephedrine and pseudoephedrine, found in asthma drugs and in decongestants. Promoted for weight-control and in energy-boosting formulas, sometimes with caffeine, which can augment the adverse effects. Can raise blood pressure and cause palpitations, nerve damage, muscle injury, psychosis, stroke, and memory loss. Several states limit sales, for instance by putting it behind pharmacists' counters. Last year, Ohio restricted all ephedrine products, including ma huang, after the death of a high-school student who'd taken an over-the-counter ephedrine product. Texas is moving in that direction, after the death of a woman who'd used an ephedra-and-caffeine herbal supplement. In August, a coalition of state drug regulators wrote to the FDA asking the agency to limit ma huang to prescription use only.

Lobelia This "Indian tobacco" acts like nicotine, though it's less potent. It can both stimulate and depress the autonomic nervous system. In low doses, lobelia dilates the lungs' bronchi and steps up breathing. As little as 50 milligrams of dried lobelia (less than a capsule) can bring on these reactions. Larger amounts could reduce breathing, drop blood pressure, induce sweating and a rapid heart beat, and cause coma and death.

Yohimbe From the bark of an African tree. Sold as a men's aphrodisiac. Its active compound, yohimbine, is a prescription drug sometimes used to treat impotence but probably is ineffective. (One medical review calls the evidence for yohimbine's efficacy "sparse and inconclusive.") An overdose can cause serious problems: weakness and nervous stimulation, followed by paralysis, fatigue, stomach disorders, and ultimately death. Georgia has branded yohimbine a "dangerous drug" and forbids selling even yohimbe herb without prescription.

Photo of Dr. Tyler courtesy Purdue University; plant photos © 1995 Steven Foster

moters often parlay suggestive results into miracle cures. A book on pycnogenol, a derivative of pine bark, is subtitled "the amazing antioxidant that fights arthritis, diabetes and stroke, and promotes prevention of heart disease and cancer." Another tome, titled "Sharks Don't Get Cancer," has helped move countless bottles of shark-cartilage capsules. But the book's thesis—that sharks possess a cancer-protective substance—remains unproved. Besides, sharks *do* get cancer, even in their cartilage.

Two plants of the same species can be 'as different as two people on a street.'

James A. Duke, USDA BOTANIST

What if you ask the clerk in the health-food store for advice? The FDA did just that in a 1993 study that sent staffers, under cover, to stores from coast to coast. Some inquired about "anything [for] my immune system." Others asked about "help for high blood pressure," or "something that works on cancer." They asked 129 times in all and got specific recommendations on what to buy 120 times. For cancer, the advice ranged from honeysuckle crystals (in a Sherman Oaks, Calif., store), to shark cartilage (Dearborn, Mich.), to coenzyme Q10, garlic, and beta-carotene (in Louisville, Ky.), to saw palmetto with vitamins (in Rocky Hill, Conn.).

Pharmacists are unlikely to give you such recommendations, but they're often clueless about the supplements sold in their drugstores. Schools of pharmacy usually don't teach courses about the uses of herbal remedies.

Consumers can still count on the Federal Trade Commission, at least, to check false advertising. An FTC lawyer told us the commission intends to go after supplement makers as vigorously as it had before the new supplement act. Last year, for example, the Commission got the corporate parent of GNC, the largest health-food chain in the country, to pay a $2.4-million civil penalty—without admitting any wrongdoing—to settle several years' worth of charges. According to the Commission, GNC had failed to substantiate disease-treatment, weight-loss, muscle-building, and endurance claims for more than 40 products.

What's in the pills?

Knowing what a supplement is supposed to do is just the first hurdle. The second is knowing whether any useful substance made it into the pills.

For starters, individual plants of the same species can differ appreciably in potency. Two such plants can be "as different as two people on a street," says James A. Duke, a U.S. Department of Agriculture botanist and specialist in medicinal plants. In extreme cases, says Duke, differences in some compounds could reach 10,000-fold. Growing conditions, storage, and handling also affect potency.

Some manufacturers are striving to standardize their products. While some companies merely put raw, ground-up plants into capsules, others—who usually identify themselves on their labels—aim for a more consistent product using pharmaceutical methods to make what are called standardized extracts. They remove extraneous matter, assay what's left for the chemicals thought responsible for the herb's action, and mix batches to achieve a consistent strength. They print labels giving details of their pills' composition and even list expiration dates (although it's not clear how they determine those dates).

But even with the best intentions, no one knows for sure the correct formulation for an herbal product. Medicinal plants typically contain a cocktail of compounds, and it's unclear whether it's individual chemicals, or particular combinations of them, that have the desired therapeutic effect. The result is a hodgepodge of products that consumers cannot sensibly compare.

Several studies have demonstrated the chaos that results from a lack of industry standards.

☐ Our tests of 10 ginseng supplements found wide variations in composition; the details are on page 699.

☐ Other tests of the ginseng content of 50 products, published last year in The Lancet, a British medical journal, found a few "ginseng" supplements that contained no ginseng at all.

☐ The Center for Science in the Public Interest, a consumer group, reported this year on its tests of several brands of garlic pills. Allicin, a compound purported to be the active cholesterol-lowering ingredient, varied more than 40-fold among brands. And the cost of a clove's worth of allicin varied from $2 down to 6 cents (for a garlic powder off the spice rack).

☐ The National Organization for Rare Disorders tested 12 brands of L-carnitine, a supplement crucial for people with a deadly metabolic disease. Carnitine is also sold to bodybuilders, supposedly to help them add muscle. Two brands offered no detectable carnitine, and another's pills varied, containing from 20 percent to 85 percent of the labeled quantity. A few other brands also showed wide pill-to-pill discrepancies—or their pills didn't disintegrate in a test simulating what occurs in the stomach.

"If there were standards for each herb," says Varro Tyler of Purdue, "it would put a lot of companies out of business."

Eventually, according to the new supplement act, the FDA must specify minimal quality controls. Standards will likely include protections from filth, methods for determining potency, and overall quality assurance—pills must contain what's listed on the label. Rules may also cover packaging, expiration dates, and lot numbers, to trace a product if something goes wrong. But those standards won't exist for at least two years.

No consistency Herbal Choice feverfew capsules contain a tan powder said to contain 0.2 percent parthenolides, to combat migraine headaches. By contrast, Nature's Way capsules weigh three times as much and hold olive-colored ground-up leaves. Which contains more parthenolides? You can't tell.

Photo of Dr. Duke by Penny King

You may see supplements labeled "USP"—for the United States Pharmacopeial Convention, the nonprofit group that sets standards for all prescription and over-the-counter drugs sold in the U.S. But at least for the next few years, any USP logo simply means that the ordinary vitamins and minerals in the pills—not the herbal or exotic ingredients—meet the group's standards. The group is considering writing standards for some herbal supplements but has not yet decided whether it will do so.

Is it safe?

You might reasonably assume that a "natural" product won't harm you. "People are often surprised by herbs—they equate 'natural' with 'safe,'" says Rossanne Philen, an epidemiologist at the Centers for Disease Control and Prevention (CDC) who handles reports of herbs' adverse effects. But her work has shown these pills can be dangerous.

Among the problems Philen sees are poisonings caused by misidentifications. The workers who pick the plants—often hired hands in developing countries—"are not Ph.D. botanists," she says. They may collect a poisonous part of the plant they're after, or the wrong plant entirely.

For instance, she told us, last year seven New Yorkers fell ill after drinking an herbal tea contaminated with a poisonous plant in the belladonna family. Three of the people were rushed to hospitals for emergency treatment. Symptoms included rapid heartbeat, fever, dilated pupils, and flushed skin.

Earlier this year, the shrub chaparral—touted as a cancer cure and blood purifier—was found to be a potential cause of serious liver damage. One woman needed a transplant after taking the herb for 10 months, according to an article in the Journal of the American Medical Association.

A Journal editorial speculated that liver damage of unknown origin might stem from herbs more often than doctors realize—and urged doctors to question their patients more carefully about the use of supplements.

Illness and death have also been tied to kombucha "mushrooms." Kombucha is really a fermenting colony of yeasts and bacteria, sold in health-food stores and passed among users, who start new colonies. The liquid is said to have tonic properties. But one Iowa woman died this spring, and another was hospitalized, after taking kombucha tea. Investigators could not definitely pin down the cause; one theory is that the tea may have reacted with a drug the dead woman took. FDA officials say there's always a risk that harmful microorganisms can taint home-grown kombucha, and they warn people with suppressed immunity to be cautious.

Perhaps the most famous outbreak of deaths from supplements was traced to the once-popular L-tryptophan. Pills containing this amino acid, which was marketed for insomnia, were linked to a painful ailment of the connective tissue and blood, eosinophilia-myalgia syndrome. Eventually, more than 1500 cases surfaced, and at least 38 people died. It's not clear if contamination at a factory or the supplement itself was to blame, but tryptophan pills are off the market.

Some supplements' contaminants are added deliberately, says the CDC's Philen. Herbal remedies may be adulterated with real drugs for extra punch—arthritis products spiked with pain killers, tranquilizers, or steroids, for example.

Patrolling the market

Even if a product has harmed someone, there's no way to be sure that it will be yanked from your local store shelves. No one is systematically tracking bad reactions.

The FDA's system for catching bad supplements is "passive surveillance," says an official at the agency's Office of Special Nutritionals. The FDA waits until reports roll in from doctors, hospitals, health agencies,

BEYOND THE HYPE

THREE HOT SELLERS

While most of the new dietary supplements are herbs, several are not—including these three, which appear to be among the hottest-selling pills in health-food stores. Here is what is known about their properties.

Melatonin. This year's craze. Synthetic versions of this human hormone are said, by the more conservative promoters, to fight insomnia and jet lag. The more daring proponents also claim that it can slow aging, fight disease, and enhance one's sex life. The authors of several new books are spreading the word.

The hormone is produced during the night by the pineal gland at the base of the brain. Studies have found that taking a fraction of a milligram can, in fact, hasten sleep; the evidence for the other claims is weak, however. Several pharmaceutical companies are hoping to turn melatonin into a prescription drug, but you can already buy melatonin in the store. The drawbacks: No one knows the right dosage, the interactions with other drugs, or the long-term effects. One brand lists extensive cautions, including warnings addressed to people with diabetes, depression, leukemia, epilepsy or autoimmune diseases, and to women who are pregnant or nursing.

Chromium picolinate. This patented form of chromium, a trace metal, is promoted for weight loss—it's claimed to target fat, spare muscle, and increase strength. Chromium helps bind insulin to cell membranes and thus may play a role in how the body uses carbohydrates. Much of the research has been done by the patent's holder; independent research does not support the claims. Picolinate's promoters say that most Americans don't get enough chromium in their diet. But documented cases of chromium deficiency are rare. In fact, animal experiments suggest that too much chromium can be harmful. And some picolinate pills, if taken as directed, would deliver several times the daily limit of chromium—200 micrograms—considered safe for people. The FDA says it has "safety concerns" and that it has received reports of adverse effects, including irregular heart beat.

Coenzyme Q10. Sellers claim the supplement can "strengthen the heart" and "inhibit the aging process." Produced in virtually every cell of the body, this substance helps convert food into energy; it's also an antioxidant. But there's disagreement over whether it works when it's swallowed.

Hidden message Manufacturers now are required to tell consumers that their health claims have not been reviewed by the U.S. Food and Drug Administration. But there is no requirement that they make that message stand out.

or individuals. Problems can take a month or more to wend their way from district offices to Washington. It often takes even longer before a pattern reveals itself. "It's a very small office in a very big area," the official told us. "Only nine people—and not all are doing adverse-effects monitoring. We tend to see only the tip of the iceberg."

FDA staffers often don't know what to make of the problems they do notice. There's no way for them to tell just how many people have suffered similar illnesses, and no way to tell how many Americans in all have been using a particular supplement. (Reports of adverse reactions to prescription drugs are sent to the FDA by the same route, but in those cases investigators begin with much more information: They know what's in the drug, who makes it, how much is prescribed, the safe dosage, and what sorts of side effects turned up during years of testing.) What's more, neither the CDC nor the American Association of Poison Control Centers have systematic mechanisms to track problems with herbs or other supplements.

The industry's attempts to regulate itself have been incomplete. The American Herbal Products Association has recommended detailed warnings on bottles of ma huang—also called ephedra—which contains amphetamine-like chemicals and can cause serious side effects. For a time the association had also asked its members to stop selling chaparral; then it suggested only that the labels on chaparral bottles include detailed cautions and a phone number to report adverse effects. The group has also recommended that a third dangerous herb, comfrey, be recommended for external use only, and not on abraded skin.

We checked a few stores to see the recommendations' effects; the results were inconsistent. We found ephedra carrying a stern warning. We found chaparral capsules, carrying a lukewarm warning and no hotline number. We also found comfrey—in capsules, for internal use.

Some states have attempted to step in. Georgia bans nonprescription sale of yohimbe, an herb carried elsewhere in health-food stores and sold as an aphrodisiac; Georgia classifies it a "dangerous drug." Several states have already restricted, or are moving to restrict, the sale of ephedra, following deaths linked to the herb or its active ingredient, ephedrine.

But there is an effort in Congress to block such local safety regulations on supplements, and to further limit Federal authority over their safety. The bill, H.R. 1951, was introduced in June; its outcome is uncertain at this writing.

Recommendations

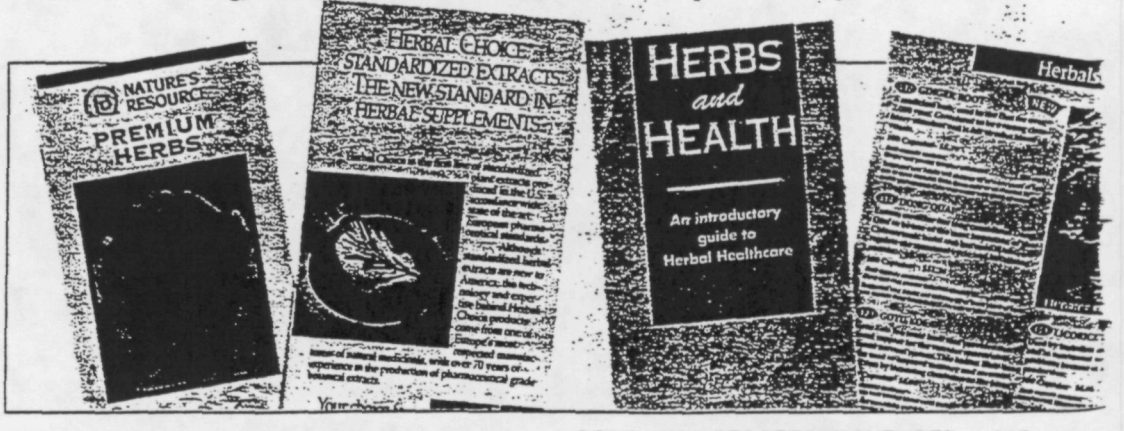
Herbal supplements have become serious business—and pose serious problems. They're sometimes expensive, they may mislead you with false promises, and they offer no assurances that what's on the label is what's inside.

We'd like to see Congress clean up the mess it's made of supplement regulations. These products should at least carry much clearer disclaimers, in large type, saying that any claims of safety and efficacy are strictly the opinions of the manufacturer and have not been confirmed by the FDA or other medical authorities. Consistent manufacturing standards should be established swiftly. Clearly dangerous supplements, like chaparral and ephedra (ma huang), should be banned immediately.

In the long run, we would like to see the United States emulate the German system for regulating herbs. There, druggists may sell herbs if there's some evidence they work, and no evidence that they are unsafe. And a national commission compiles monographs discussing each herb's pros and cons, which are then published.

If you want to try a supplement despite the uncertainties, don't rely on what's printed on the packages or in pamphlets. Do your best to seek out independent sources of information about what the herbs and other supplements are supposed to do. We recommend two books, both by Varro Tyler, an expert in the medicinal use of plants: *The Honest Herbal—A Sensible Guide to the Use of Herbs and Related Remedies* (third edition, 1993); and *Herbs of Choice—The Therapeutic Use of Phytomedicinals* (1994). Both are published by Pharmaceutical

Unchecked claims Consumers typically get much of their information about supplements from pamphlets and books whose accuracy gets little official scrutiny. That is unlikely to change under the new law.



BUZZWORDS ON BOTTLES

Supplement bottles abound with impressive terms. Many turn out to be elaborate ways of describing the commonplace.

Antioxidants Compounds—such as vitamin C, vitamin E, and beta carotene—presently taking much of the credit for the apparent protective effects of fruits and vegetables. Antioxidants control "free radicals," which damage cells through oxidation. Some marketers suggest all antioxidants can prevent cancer and heart disease, but the evidence from controlled clinical trials is mixed and suggests that different antioxidants have different effects.

Energy Sometimes a euphemism for stimulants like caffeine and ephedra. In other cases, a perfectly safe throwaway word, since all digestible plant products provide chemical energy, measured in calories.

Enzymes Proteins that work as catalysts to enhance chemical reactions. (We've seen products containing cytochrome C, involved in cells' energy production, and papain, a papaya enzyme.) But enzymes taken orally usually are broken down by digestion, like other protein, and are thus of no special use to the body.

Phytonutrients From "phyto," Greek for plant, these botanical substances are a new supplement category. Some are extracted from vegetables such as broccoli. It's too early to say whether the manufacturers have picked the right active ingredients (there may be thousands to choose from), or whether the amount packed into a pill is meaningful.

RNA and DNA Genetic material said to rejuvenate cells, enhance memory, prevent wrinkling. Already present in many foods anyway. Often destroyed by digestion.

Products Press (Haworth); the first book is organized by herb, the second by disease.

Here are several other suggestions for playing it safe:

☐ Before trying a supplement, consider changes to your diet or lifestyle that might accomplish your goals. If you have high cholesterol, for example, cut your intake of saturated fat and begin an exercise program before you consider taking garlic pills.

☐ Check with your doctor before taking an herb or other supplement. Many people don't, for fear of looking silly or getting a lecture. But it's worth the risk of embarrassment. A supplement may interact with a drug you take or pose a serious side effect. And the doctor may know of an effective conventional treatment you should try first.

☐ Pregnant and nursing women and anyone with chronic and serious health problems should not take herbal supplements, unless their doctor gives the green light.

☐ Check the warnings on packages and on related material. Start with small doses.

☐ Buy herbs that at least claim to be "standardized"—so you have a fighting chance of consistent contents from pill to pill.

☐ Stick to single-herb products, not combinations, whose actions might be hard to sort out.

☐ Be alert to the herb's effects—positive and negative. If you can track progress objectively—with cholesterol tests, say, or by keeping tabs on your urinary flow if you're taking a prostate remedy—you'll be less susceptible to the power of suggestion.

☐ Stop immediately if there's a problem, and call the doctor. For instance, abdominal pain, darkened urine, and jaundice can signal liver complications that an herb may have brought on.

☐ If you think a product made you sick or otherwise harmed you, the FDA advises you to contact your doctor, who should then call the agency's MedWatch hotline for professionals to report adverse effects. The agency also suggests contacting your state and local health departments and consumer protection agency. ■